

HUMAN EMBRYO TRANSFER

HEARINGS BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY HOUSE OF REPRESENTATIVES NINETY-EIGHTH CONGRESS

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HUMAN EMBRYO TRANSFER

WEDNESDAY, AUGUST 8, 1984

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to call, at 9:40 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. GORE. The subcommittee will come to order, please.

Other members are on their way, and I would like to ask unanimous consent that the statement—opening statements of other members be included in the record immediately after my own. But we've got clearance to go ahead with the hearing and we're going to start since we have a long day and since the full committee is in session conducting business, so we're going to have to—to move right ahead.

Let me begin with my opening statement and then we will go to the first panel.

Just over 6 years ago, Louise Brown, the world's first so-called test tube baby was born in Great Britain. Since that time, in vitro fertilization clinics, or IVF clinics, have been established in at least 10 other countries, including the United States, enabling hundreds of infertile couples to have children. These initial in vitro fertilization programs have now been expanded to include techniques such as embryo transfer, or the transfer of an embryo from one woman to another, and cryopreservation, or the freezing of an embryo or more technically, a cytotblast.

As the statistics show, these techniques, known collectively as alternative reproductive technologies, have gained much currency; they now offer great hope, and in some cases, the only hope, to infertile couples to have children. Approximately 600 children have been born worldwide as a result of in vitro fertilization and there have been two or possibly three involving frozen embryos.

I use the phrase "possibly three" because there is some uncertainty and controversy surrounding a 1978 birth in India which the doctor said involved a frozen embryo but the scientific regiment surrounding it was not rigid enough to permit an independent assessment.

As with many tech—as with many new technologies, the potential use of some of these techniques challenge our traditional notions about parenting, adoption, inheritance, and motherhood, and they are forcing a reevaluation of both our legal and ethical understandings.

Last week, the British Government released, after 18 months of study, a report of its Committee of Inquiry Into Human Fertilization and Embryology. The Warnock committee, as the British committee is known, put its stamp of approval on the use of in vitro fertilization and artificial insemination by donor but rejected at this time lavage and freezing of eggs. Lavage being, of course, the donation of a fertilized embryo removed from one woman and implanted into another.

The committee called as well for extensive licensing of clinics and providers to regulate both research and certain infertility services and sought to discourage use of surrogate mothers, even recommending the criminalization of some aspects of surrogate motherhood.

In Australia, where the world's first successful, scientifically validated birth occurred from a frozen embryo last year, the Waller commission is studying the ethical and legal implications of that birth and the commission's study is expected to be complete next month.

Unfortunately, here in the United States, we have yet to grapple with these issues so that the practices have developed and are being used without any consensus about where the appropriate limits are. Procedures adopted by the American Fertility Society and by others seek to resolve many of the overall questions but because of differences in State law—and in many cases the total absence of law—there is a great deal of uncertainty. One of our witnesses will describe our own legal structure relative to alternative reproduction technologies as "procrustean".

Today and tomorrow, we hope to begin a responsible dialog on these sensitive issues and look at how a consensus on these issues might be developed. Fortunately, we will be assisted in this difficult task by the most prominent people in the fields of alternative reproduction technologies as "procrustean."

Today, we will focus on questions of medicine and science and look at the legal dilemmas posed by these new techniques. We will hear today, as well, how one institution—Vanderbilt University—established an infertility treatment center and wrestled with its own to solve these difficult dilemmas.

Tomorrow, we will hear testimony from two doctors who are pioneering the new techniques of lavage and cryopreservation, and we will hear from patients who will tell us about their wishes and their conflicts. Tomorrow we will also turn our attention to a broad examination of the many ethical questions posed by these new techniques.

In advance I'd like to thank all of our witnesses for coming here and we're going to go right into the first one. We have a witness and then we have three panels, and we're going to try to move right along today, so let's go ahead and get started.

Our witness is Dr. Clifford Grobstein, professor of biological science and public policy at the University of California at San Diego at La Jolla. And, Dr. Grobstein, if you could join us at the witness table. We're delighted to welcome you back because quite some time ago we had hearings on genetic therapy and you were of great assistance to us during that inquiry and we're glad to call on your expertise and wisdom again. And without objection, your entire

prepared statement will be put into the record at this point, and if you care to summarize any portion of it, feel free to do so. If you want to present it as it is written, that is also fine, it's up to you. But please proceed.

STATEMENT OF CLIFFORD GROBSTEIN, PROFESSOR OF BIOLOGICAL SCIENCE AND PUBLIC POLICY, UNIVERSITY OF CALIFORNIA, SAN DIEGO

Mr. GROBSTEIN. Thank you very much. Mr. Chairman, members of the subcommittee, ladies and gentlemen.

I'm very happy to have the opportunity to testify again before this subcommittee, this time on the status and implications of human embryo transfer.

As the chairman has just mentioned, my earlier testimony in 1982 related to human gene transfer.

Mr. GORE. I'm not sure that microphone is on, Dr. Grobstein. Maybe if you can slide the other one over there, the two of them together will—

Mr. GROBSTEIN. I hope it will not only increase the volume but also the quality.

The two subjects of in vitro fertilization and embryo transfer and human gene transfer are not without connection. While they rose out of different technical fields and they serve different medical objectives and initially raise different policy issues, they also have important similarities in policy terms.

The similarities derive from the fact that both gene and embryo transfer are technical interventions that open a whole nest of new options in human reproduction. In turn, some of these options disturb deep and longstanding social attitudes and traditions that are locked into moral and religious codes.

Moreover, the two kinds of intervention are likely to converge and interact because gene transfer to early embryos, rendered accessible in humans by external fertilization, is a feasible route for insertion of genetic instructions that may be transmitted to subsequent generations.

These facts led me to argue, in my earlier appearance before you, that the two should be considered by the same oversight mechanism. It is, indeed, my view that a single oversight mechanism should deal with the entire spectrum of new human reproductive options as they are now envisioned. Some of these options, though seemingly bizarre today, may have their important place in the human future.

Against this background, I will briefly recapitulate where we have come from and where we are with IVF and embryo transfer. They developed out of extensive basic laboratory studies of mammalian reproduction, studies that are still far from running their course.

As a result of knowledge already acquired it is possible to remove early embryos from a number of kinds of laboratory and farm animals, to freeze them if desirable, to thaw them for significant but not unlimited continued development externally, and to transfer them to a properly prepared uterus for progression to term, either in the original donor or in a foster mother.

The application of this technology to animal production is expanding rapidly, in both laboratory and farm species. Meanwhile, the technology has been successfully applied to humans in the medical realm. It is in wide use to relieve human infertility in the United States and around the world. It takes only a little imagination to recognize the importance of this technology not only in terrestrial agriculture but in extraterrestrial colonization.

Even if there were no motivation for direct application to the human species, there would be ample motivation for its continued advance and refinement to serve other objectives. And as it advances there will be continuing temptation to use it on our own species if it seems desirable or necessary.

Meanwhile, molecular genetic technology is growing in power, again, both for basic studies and for achievement of practical objectives. Among the practical possibilities is therapy for human genetic disease. No successful application has yet been reported but a number of investigators believe that the threshold is not far off.

What is the general nature of the issues that are common to these two new areas of reproductive options? Seen in their medical context both can be viewed as imaginative and constructive approaches to alleviation and management of human ailments. In gene transfer the ailments are a large class of genetic diseases of great severity. In IVF and embryo transfer, the target is infertility in married couples that seriously reduces life satisfaction.

Ordinarily, medical efforts to deal with such problems are subject only to test for safety and efficacy. However, in these cases other issues have been raised and these are the ones of special interest here.

In gene therapy a key background issue is whether intervention in hereditary mechanisms is improper and in some sense dangerous. The possible impropriety derives from the feeling that heredity relates to fundamental nature—in this case, human nature—and should not be subject to self-manipulation.

The suggestion of danger is based on the possibility that individual human whim may prove nefarious and detrimental to humanity as a whole. Certainly there are precedents for such concern.

In IVF and embryo transfer similar concerns are voiced but in a little different form. The suggestion of impropriety in this instance relates to intervention in the somewhat mysterious and, until now, largely hidden process of genesis of a new human individual.

This process has been regarded as sacrosanct and privileged against invasion or intervention. To open such a process to possible meddlesome manipulation is seen as particularly disturbing because it threatens disruptive control of the central individual core: the personal self.

What is common to these concerns in the two areas is the fear that while important medical benefits may accrue, it may be at an unacceptable price in terms of fundamental human values. What unites the two areas and characterizes much of the spectrum of new reproductive options is its confrontation with truly bedrock human reactions and anxieties embedded in long tradition. It is this common aspect that seems to argue strongly for a joint oversight mechanism.

However, beside the general and common aspect of gene and embryo transfer each raises its own special issues as well. In IVF and embryo transfer the most immediate issue is embryo freezing. There is still legitimate ground to question this procedure with respect to safety. What is the probability that thawed embryos will give rise to defective offspring? Present information is reassuring but not completely persuasive. With respect to humans, the first scattered and incomplete reports record a normal birth, a spontaneous abortion, and no abnormalities. Taken by themselves these data allow no certain conclusion to be drawn.

Much more information is available on animals, particularly the cow and mouse. In the cow, embryo loss remains a problem in terms of economic efficiency and efforts continue to improve the freezing technique so as to minimize loss.

It is of interest that despite wide use of freezing in cattle breeding there are no reports of heightened incidence of abnormality.

It should be noted, however, that it is not clear whether results on one species can be reliably projected to another. Therefore, any additional results of transfer of frozen/thawed human embryos will be watched with great interest.

However important the safety issue, there is more than safety at stake in human embryo freezing. Freezing essentially puts the embryo into a state of suspended animation and, in so doing, greatly increases the number of subsequent options. The immediate clinical advantage is preservation of extra embryos obtained by one laparoscopy so that they may be transferred, if needed, in a subsequent menstrual cycle.

Other than safety, this option creates no new policy issue, it is simply an improvement of the IVF procedure within its original medical objective to circumvent infertility in a married couple.

However, once the embryos are frozen, additional options and issues are presented. As example, if a first attempt at transfer to the uterus of the donor were successful, stored frozen embryos might be used for a second pregnancy for the donor at a later time. This could be done at the convenience of the donor couple, providing a limited kind of family planning. By extension, and assuming increased effectiveness of embryo transfer, this may offer a procedure for complete family planning. For example, it can be imagined that even though not infertile, a couple might request external fertilization in order to freeze a set of embryos early in their marriage when their fertility is highest. They might then undergo sterilization, eliminating the need for contraception, followed by embryo transfer at their desired times. They could thus fully control their family planning.

Were such storage of frozen embryos to occur frequently the dilemma recently presented by two frozen embryos stored in Melbourne might recur commonly, clearly forcing clarification of the ethical and legal status of the early human embryo.

In the Melbourne situation the issue arose because the donor couple, who were U.S. citizens, had died in an airplane accident. In settlement of their estate, question arose as to possible claim for inheritance on behalf of the embryos. The rights of such embryos, previously an issue primarily with respect to abortion, are now pre-

sented in an unprecedented way—relating to living entities that exist independently of both mother and father.

Thus, these and other imaginable options opened by IVF and embryo transfer constitute a new area needing oversight and possibly policy decision.

There are a number of ways in which such oversight might provided—be provided. One is a commission of the kind that this subcommittee recommended for gene transfer, whether it be a second commission or, preferably, a broadened version of the first.

I believe that such a commission could make an important contribution and I favor legislation to that end.

Such oversight began several years ago in England and Australia where in vitro fertilization and embryo transfer were pioneered. In both countries, public bodies began studies of the issues involved in respect to developing controversy.

The Report of the Warnock Committee of Inquiry, released last month in Great Britain following more than 2 years of study, makes several recommendations that bear on policy toward frozen human embryos.

It recommends, for example, that no embryo that is not in utero at the date of the death of the father shall be taken into account "for the purposes of succession to or inheritance from" the father.

This recommendation would settle the issue raised in connection with the two frozen embryos in Melbourne. However, several additional recommendations are made that bear on the status of early human embryos external to the mother. It is recommended that "no right of ownership in a human embryo" shall be recognized in law. When a donating couple dies, the right to use or dispose of frozen/stored embryos "should pass to the storage authority." To the degree that these stipulations appear to deny status to the early human embryo, it is recommended that "The embryo of the human species should be afforded some protection in law."

The recommendations of the Warnock Inquiry are likely to stir considerable debate in Great Britain before policies are clearly set. The central recommendation is for the "establishment of a new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control."

The new body is intended to be both advisory and executive. Its advisory activities would be directed both to active professionals in the field and to government to protect the public interest. Its executive activity would be to license and monitor both health care and research activities.

In the latter activity, attention would focus on the purposes of the proposed clinical application of research—of central importance in evaluating interventions in the human species.

While the Inquiry has endorsed a broad scope of applications using in vitro fertilization and embryo transfer, the recommendations also impose specific restrictions. For example, laboratory maintenance of human embryos would be limited to 14 days after fertilization and it would be "a criminal offense to handle or to use as a research subject any live human embryo derived from in vitro fertilization beyond that limit."

The availability of the Warnock Inquiry clearly will be helpful in the United States but it does not displace a similar effort here that is tuned to our needs and that provides our own deliberative period before setting objectives and devising the best mechanisms for realizing them.

Accordingly, we should move forward with dispatch to establish a suitable deliberative mechanism for the whole range of new human reproductive options. In so doing, the following should be background objectives:

One, to define the status of the human embryo so as to protect the unique value it has in human society.

Two, to define and protect parental rights with respect to the new options.

Three, to alleviate infertility while respecting other values.

Four, to reduce genetic disease and birth defects as feasible.

Five, to maximize freedom of research while protecting essential human rights.

Six, to reduce legal conflict and confusion.

Seven, to minimize regulatory actions that may undermine professional initiative and responsibilities.

Eight, to maximize public understanding and participation.

These objectives clearly merit wide discussion, appropriately led by a national commission. I hope that such a commission, broadly charged to examine new human reproductive options, can be brought into operation by statute without delay.

Thank you very much for the opportunity to appear before you.

[The prepared statement of Mr. Grobstein follows:]

Testimony Before the U.S. House of Representatives Subcommittee

On Investigations and Oversight on August 8, 1984

by: Clifford Grobstein, Professor of Biological Science & Public Policy
University of California, San Diego

Mr. Chairman, Members of the Sub-committee, Ladies and Gentlemen:

I am happy to have the opportunity to testify again before your sub-committee, this time on the status and implications of human embryo transfer. My earlier testimony in 1982 related to human gene transfer. In endorsing the establishment of a special commission to deliberate on that important matter I noted my belief that similar deliberation is needed on issues raised by external human fertilization and embryo transfer. I am pleased to be able to return to amplify my view now that you have this matter under consideration.

The two subjects are not without connection. While they arose out of different technical fields, serve different medical objectives and initially raise different policy issues, they also have important similarities in policy terms. I would like to begin by underlining the similarities.

The similarities derive from the fact that both gene and embryo transfer are technical interventions that open a whole nest of new options in human reproduction. In turn, some of these options disturb deep and long-standing social attitudes and traditions that are locked into moral and religious codes. Moreover, the two kinds of intervention

are likely to converge and interact because gene transfer to early embryos, rendered accessible in humans by external fertilization, is a feasible route for insertion of genetic instructions that may be transmitted to subsequent generations. These facts led me to argue, in my earlier appearance before you, that the two should be considered by the same oversight mechanism. It is, indeed, my view that a single oversight mechanism should deal with the entire spectrum of new human reproductive options as they are now envisioned.

Such an oversight mechanism should provide an arena for continuing public discussion, not only of the options that have already been presented by advancing science and technology but of those that can be expected to arise in coming decades. In my view, we have so far only seen the beginning of reproductive options that will continue to emerge through the early years of the new millennium. Moreover, some of these options—though seemingly bizarre today—may have their important place in the human future.

Against this background I will briefly recapitulate where we have come from and where we are with embryo and gene transfer. External human fertilization (IVF) and embryo transfer developed out of extensive basic laboratory studies of mammalian reproduction, studies that are still far from running their course. As a result of knowledge already acquired it is possible to remove early embryos from a number of kinds of laboratory and farm animals, to freeze them if desirable, to thaw them for significant but not unlimited continued development externally, and to transfer them to a properly prepared uterus for progression to term, either in the original donor or in a foster mother.

The application of this technology to animal production is expanding rapidly, in both laboratory and farm species. Meanwhile, the technology has been successfully applied to humans in the medical realm. It is in wide use to relieve human infertility in the U.S. and around the world. It takes only a little imagination to recognize the importance of this technology not only in terrestrial agriculture but in extraterrestrial colonization. Even if there were no motivation for direct application to the human species, there would be ample motivation for its continued advance and refinement to serve other objectives. And as it advances there will be continuing temptation to use it on our own species if it seems desirable or necessary.

Gene therapy also developed out of extensive basic laboratory studies, in this case of heredity—particularly in bacteria and viruses. Here again basic studies have hardly reached their peak, rather they are steadily enlarging possible practical applications. Genes as elementary units of heredity are now readily isolated; they can be transferred under favorable circumstances from one individual to another whether they be of the same or different species. It also is possible to modify or even synthesize genes almost at will.

The resulting molecular genetic technology is growing in power, again both for basic studies and for achievement of practical objectives. Among the practical possibilities is therapy for human genetic disease. No successful application has yet been reported but a number of investigators believe that the threshold is not far off.

Beyond this, gene transfer to early embryos in the laboratory has led to hereditary change that is transmissible to succeeding

generations. There are still many uncertainties and unknowns in this process. It would be premature technically to consider application of the technique to humans even if legitimate objectives were defined. The definition of legitimate objectives is one of the major issues needing deliberation by an oversight mechanism. There are those who believe that there can be no such objectives and that all further effort in this direction should be abandoned. They would do well to ponder the possible applicability of this technology to a post-nuclear-war population attempting to recover reproductively against a considerably elevated incidence of genetic disease resulting from radiation exposure. Under these circumstances, germ-line genetic repair might be essential for survival of the human species.

What is the general nature of the issues that are common to these two new areas of reproductive options? Seen in their medical context both can be viewed as imaginative and constructive approaches to alleviation and management of human ailments. In gene transfer the ailments are a large class of genetic diseases of great severity. In IVF and embryo transfer the target is infertility in married couples that seriously reduces life satisfaction. Ordinarily, medical efforts to deal with such problems are subject only to test for safety and efficacy. However, in these cases other issues have been raised and these are the ones of special interest here.

In gene therapy a key background issue is whether intervention in hereditary mechanisms is improper and in some sense dangerous. The possible impropriety derives from the feeling that heredity relates to fundamental nature—in this case human nature—and should not be subject to

self-manipulation. The suggestion of danger is based on the possibility that individual human whim may prove nefarious and detrimental to humanity as a whole. Certainly there are precedents for such concern.

In embryo transfer similar concerns are voiced but in a little different form. The suggestion of impropriety in this instance relates to intervention in the somewhat mysterious and, until now, largely hidden process of genesis of a new human individual. This process has been regarded as sacrosanct and privileged against invasion or intervention. To open such a process to possible meddlesome manipulation is seen as particularly disturbing because it threatens disruptive control of the central individual core--the personal self.

What is common to these concerns in the two areas is the fear that while important medical benefits may accrue, it may be at an unacceptable price in terms of fundamental human values. What unites the two areas and characterizes much of the spectrum of new reproductive options is its confrontation with truly bedrock human reactions and anxieties embedded in long tradition. It is this common aspect that seems to argue strongly for a joint oversight mechanism.

However, beside the general and common aspect of gene and embryo transfer each raises its own special issues as well. In gene transfer the most immediate special issue, as came out clearly in your earlier hearing, relates to its possible use to repair genetic disease expressed in ordinary body or somatic cells. What knowledge will be sufficient to justify a clinical trial of this form of therapy? Although there is not universal agreement, there is some consensus among those who have been thinking about the matter that this is not a new kind of issue since, as

in traditional therapy, effects will be confined to the treated individuals.

Many, however, see gene transfer applied to human germ-line cells as a more difficult and longer term issue because effects would be passed on to descendant generations and would, in some degree, modify the human gene pool. Moreover, success in eliminating genetic defects might trigger efforts to introduce "improvements," with all of the complications and difficulties that judgments in this area would entail. This eugenic issue has long been the subject of controversy and remains always in the background of discussion of gene transfer. It clearly is a major topic for deliberative oversight.

Turning to IVF and embryo transfer, the most immediate issue is embryo freezing. There is still legitimate ground to question this procedure with respect to safety. What is the probability that thawed embryos will give rise to defective offspring? Present information is reassuring but not completely persuasive. With respect to humans the first scattered and incomplete reports record a normal birth, a spontaneous abortion and no abnormalities. Taken by themselves these data allow no certain conclusion to be drawn.

Much more information is available on animals, particularly the cow and mouse. In the cow, embryo loss remains a problem in terms of economic efficiency and efforts continue to improve the freezing technique so as to minimize loss. However, despite wide use of freezing in cattle breeding there are no reports of heightened incidence of abnormality.

Research on various cryoprotectants and freeze-thaw regimens has led to a steady improvement in methods. Over the past decade, increasing proportions of both domestic animal and laboratory mouse embryos have remained viable and capable of continued development after thawing and transfer to the uterus. For example, as many as 90% of frozen 8-cell mouse embryos develop in vitro after thawing and fully two-thirds of once frozen embryos yield offspring, a rate of success comparable to that achieved using embryos that have never been frozen. The offspring resulting from such experiments show no evidence of abnormality attributable to freeze-thawing. This does not necessarily mean that the procedure causes no damage. Severely damaged embryos may undergo spontaneous elimination early in pregnancy, while those only slightly injured may repair themselves.

It should be noted that it is not clear whether results on one species can be reliably projected to another. Therefore, any additional results of transfer of frozen-thawed human embryos will be watched with great interest.

However important the safety issue, there is more than safety at stake in considering human embryo freezing. Freezing essentially puts the embryo into a state of suspended animation and, in so doing, greatly increases the number of options. The immediate clinical advantage sought is preservation of extra embryos obtained by one laparoscopy so that they may be transferred, if needed, in a subsequent menstrual cycle. Other than safety this creates no new policy issue, it is simply an improvement of the IVF procedure within its original medical objective to circumvent infertility in a married couple.

However, once the embryos are frozen additional options and issues are presented. As example, if a first attempt at transfer to the uterus of the donor were successful, stored frozen embryos might be used for a second pregnancy at a later time. This could be done at the convenience of the donor couple, providing a limited kind of family planning. By extension, and assuming increased effectiveness of embryo transfer, this may offer a procedure for complete family planning. Even though not infertile, a couple might request external fertilization in order to freeze a set of embryos early in their marriage when their fertility is highest. They might then undergo sterilization, eliminating the need for contraception, followed by embryo transfer at their desired times. They could thus fully control their family planning.

Were such storage of frozen embryos to occur frequently the dilemma recently presented by two frozen embryos stored in Melbourne might recur commonly, clearly forcing clarification of the ethical and legal status of the early human embryo. In the Melbourne situation the issue arose because the donor couple, who were U.S. citizens, had died in an airplane accident. In settlement of their estate, question arose as to possible claim for inheritance on behalf of the embryos. The rights of such embryos, previously an issue primarily with respect to abortion, are now presented in an unprecedented way— relating to living entities that exist independently of both mother and father.

Another set of options posing new policy issues involves transfer of embryos to the uterus of a non-donor, whether immediately or following a period in frozen storage. An example has been referred to as embryo adoption. A possible scenario supposes that following successful

transfer of unfrozen embryos to the uterus of the donor several embryos that had been frozen remain and are no longer wanted by the donor for her own use. Accordingly, she and her husband agree to make them available to an infertile couple in which the wife cannot produce eggs but has a functional uterus. Transfer of the thawed embryos is successful, the recipient goes through a normal pregnancy and the couple have a child (as in postnatal adoption) but toward whom there may be greater feelings of kinship because the child comes from the wife's "own body." The process requires a distinction between two aspects of motherhood--genetic and gestational. Other third party involvements in the procreative function are readily imaginable (for example, surrogacy). All require deliberative consideration in an oversight arena.

Thus, these and other imaginable options opened by IVF and embryo transfer constitute a new area needing oversight and possibly policy decision. The area is at least as immediate and in some ways more complex than gene transfer. The term "oversight" in this context is intended to mean deliberative consideration by interested parties, beyond doctor and patient, in a common public arena. I repeat my view that the agenda for such oversight should include all newly emerging reproductive options for the human species, whether hereditary or developmental, since these options are likely to interact and they have an underlying common basis of concern.

There are a number of ways in which such oversight might be provided. One is a commission of the kind that this subcommittee recommended for gene transfer, whether it be a second commission or, preferably, a broadened version of the first. I believe that such a commis-

sion could make an important contribution and I favor legislation to that end. This is not to say, however, that a commission is the only way to go or that establishment of a commission precludes other options. The issues raised are so fundamental for various faiths and value systems that deliberation within private groups is as important as deliberation at the public level. The essential objective is to initiate broad consideration and consensus-building that can responsibly anticipate the new technological options that lie ahead. Activities in both the private and public sectors can contribute to the process.

Such oversight began several years ago with respect to IVF and embryo transfer in England and Australia, where these techniques were pioneered. In both countries public bodies began studies of the issues involved, in response to developing controversy. The Report of the Warnock Committee of Inquiry, released this month in Great Britain following more than two years of study, makes several recommendations that bear on policy toward frozen human embryos. It recommends, for example, that no embryo that is not in utero at the date of the death of the father shall be taken into account "for the purposes of succession to or inheritance from" the father.

This recommendation essentially would settle the issue raised in connection with the two frozen embryos in Melbourne. However, several additional recommendations are made that bear on the status of early human embryos external to the mother. It is recommended that "No right of ownership in a human embryo" shall be recognized in law. When a donating couple dies, the right to use or dispose of frozen-stored embryos "should pass to the storage authority." To the degree that these

stipulations appear to deny status to the early human embryo, it is recommended that "The embryo of the human species should be afforded some protection in law."

These are, of course, recommendations to meet the circumstances and needs of the United Kingdom and may or may not be appropriate for the U.S.. The major lesson to be drawn, however, is that the British recognized some time ago that a mechanism of policy formation was needed to deal with the special new problems raised by IVF and embryo transfer. They are ahead of us in this as they were in demonstrating the new technology. The same is true in the Australian state of Victoria where IVF also was pioneered.

The recommendations of the Warnock Inquiry are likely to stir considerable debate before policies are clearly set in Great Britain. The central recommendation is for the "establishment of a new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control." The functions of the new body are intended to be both advisory and executive. Its advisory activities would be directed both to active professionals in the field and to government to protect the public interest. Its executive activity would be to license and monitor both health care and research activities. In the latter activity attention would focus on the purposes of the proposed clinical application or research -- of central importance in evaluating interventions in the human species.

While the Inquiry has endorsed a broad scope of applications using IVF and embryo transfer, the recommendations also impose specific restrictions. For example, laboratory maintenance of human embryos would

be limited to 14 days after fertilization and it would be "a criminal offense to handle or to use as a research subject any live human embryo derived from in vitro fertilization beyond that limit."

The availability of the Warnock Inquiry clearly will be helpful in the U.S. but it does not displace a similar effort here that is tuned to our needs and that provides our own deliberative period before setting objectives and devising the best mechanisms for realizing them. Accordingly, we should move forward with dispatch to establish a suitable deliberative mechanism for the whole range of new human reproductive options. In so doing, the following should be background objectives:

1. To define the status of the human embryo so as to protect the unique value it has in human society.
2. To define and protect parental rights with respect to the new options.
3. To alleviate infertility while respecting other values.
4. To reduce genetic disease and birth defects as feasible.
5. To maximize freedom of research while protecting essential human rights.
6. To reduce legal conflict and confusion.
7. To minimize regulatory actions that may undermine professional initiative and responsibilities.
8. To maximize public understanding and participation.

These objectives clearly merit wide discussion, appropriately led by a national commission. I hope that such a commission, broadly charged to examine new human reproductive options can be brought into operation by statute without delay.

Thank you very much for the opportunity to appear before you.

Mr. GORE. Thank you very much, Dr. Grobstein. I appreciate you getting us off to such a good start.

One of the concerns which led us to have this hearing today and to conduct the investigation that we have conducted over the past several months is very simply that the scientific developments are occurring a lot more rapidly than improvements to our—the ethical and legal structures within which these new scientific and technological developments take place. Other countries have moved much faster than we have to consider where the appropriate limits are and what are the values that are at risk; how should we proceed in a careful and sensitive way? And you have given a great deal of thought to precisely that question.

There are several related questions I want to explore with you here today, but to begin with, you recommend that we have a national commission, presidential commission, whatever we want to call it, that is charged with a mandate broad enough to cover this technology and help our country understand better what the ethical dilemmas are that are arising out of this new technology so we can avoid some of the pitfalls and see some of the opportunities that are clearly there.

This subcommittee earlier, after our hearings on human genetic engineering 2 years ago, almost 2 years ago, recommended to the full House of Representatives the establishment of a Commission on Human Genetic Engineering. The House of Representatives agreed and passed a bill creating such a commission but the other body, as we refer to the U.S. Senate, has not passed that. But what you're saying here today is that we ought to pursue that vigorously, and in so doing, we ought to make certain that it's a mandate, that the mandate of this commission is broad enough to also include the subject of embryo transfer and alternative reproductive technologies simply because you see them as intertwined, human genetic engineering and alternative reproductive technologies.

Now, the reason they are intertwined—you correct me if I'm getting it wrong—is that the availability, I mean the creation of embryos outside of the body is what makes it possible to engage in these new genetic manipulations that many scientists have discussed. The technology of embryo transfer and in vitro fertilization and cryopreservation, all of those technologies ought to be considered as part of the same continuum on which rests human genetic engineering as well.

Is that essentially your view?

Mr. GROBSTEIN. Yes, I think it is the case that the two technologies will reinforce each other, so to speak. It is the case that inadvertently, at least in terms of the objectives of the people who are developing in vitro fertilization—they have made accessible early stages of human development that are in their stage identical with those that are being used in investigations on the mouse where it is clear that it is possible to insert genetic information that will influence the developing embryo and the adult derived; and also will influence subsequent generations in the mouse. So that the stages that are being used for laboratory transfer of genetic information in mammals are the same stages that are made accessible in the process of in vitro fertilization in humans.

So technically, the two come together at that point, and information in one area can be utilized in the other area. They are conjoint in that sense.

Second, I'm suggesting that many of the issues that are raised in each area, the kinds of moral, ethical issues that are raised, the kinds of social mechanisms required to deal with the impact, that these two overlap. Now, for those two reasons it seems to me that we deal here essentially with one new problem, which is the fact that technology is impinging on very fundamental human values. And I think these can be perhaps best sorted out in one deliberative context.

Mr. GORE. Now, one option for us to—is to just sit back and watch the science develop and not worry about the bioethical questions. Why do you think that would be a mistake?

Mr. GROBSTEIN. Well, I can't say for certain that it will be. It does seem to me that we will be better off to try to anticipate these issues as they come up and to try to deal with them in some consensual, generalizable way.

Mr. GORE. Yeah.

Mr. GROBSTEIN. Otherwise, I think we'll find ourselves dealing piecemeal and conceivably in contradictory ways with the various specific issues that come up.

Mr. GORE. Well, I certainly agree with you and, of course, that's one of the reasons why we're having this hearing.

Let's talk about some of the possibilities. When you talk about consensus, it may be difficult to find any consensus in this area, but there are some things about which a consensus may be possible. Let's talk about some of the technical possibilities in an effort to define the areas of consensus.

Technically it is possible today to clone a human embryo. Correct?

Mr. GROBSTEIN. That depends on which meaning of the word clone you use.

Mr. GORE. To precisely replicate a human embryo, to—in other words, you have one embryo with a set of specific characteristics determined by its genes and through a scientific process you can cut that—I'm using the word embryo, I guess the technical word is cytotblast; right?

Mr. GROBSTEIN. Well, I assume you're talking about the early cleavage stages of the embryo when—

Mr. GORE. Yes.

Mr. GROBSTEIN [continuing]. There are several cells, two, four, or eight cells present, following the division of the initial fertilized egg. And under those circumstances, not demonstrated in humans, but demonstrated in mice and other—

Mr. GORE. Horses, cattle?

Mr. GROBSTEIN [continuing]. Species—horses. It has been shown that if you separate those initial cells, that each of them is capable of giving rise to a complete embryo and a complete individual. And those individuals then will have the same hereditary constitution and in that sense they will represent a clone.

However, the more common term to use for that is twinning, which does produce two individuals, two or more individuals, with the same hereditary constitution. That can be artificially done, and

then you have artificially produced twins, and those twins would belong to a clone.

I am emphasizing this point because the term clone is used for another procedure in which the nucleus of an adult cell—

Mr. GORE. Yes.

Mr. GROBSTEIN [continuing]. Is put into an embryonic cell whose own nucleus has been removed. And this would be intergenerational cloning—

Mr. GORE. Yes.

Mr. GROBSTEIN [continuing]. And you would thereby produce, if it could be done, an individual of the same hereditary constitution as the donor of the nucleus.

Mr. GORE. But that's not possible at the present time; because after maturation and after so many cell divisions, the genetic information in the cell's nucleus, while still present, is partially irretrievable, that is, much of the genetic information will not express itself in an adult cell. So the classic science fiction view of cloning is still science fiction—you can't take a fingernail scraping and take the genetic information from that cell and give rise to a new individual with identical genetic characteristics simply because that genetic information will not fully express itself.

But in the embryonic stage all of that information is still retrievable. The specialization of cells has not yet taken place and when you take part of the split embryo and place it in a new protective—or whatever you call that thing—it will then grow into an identical replica of the one it was taken from.

I mean, that's what's been done with horses, cattle, mice, et cetera, and they have raised essentially—well, exactly identical animals through that procedure.

Now, is it your view that that would be unethical if attempted on human beings?

Mr. GROBSTEIN. You are talking about now the twinning type?

Mr. GORE. Yes.

Mr. GROBSTEIN. Yes; I think I would answer that it could be either ethical or unethical depending on the purposes. I am more concerned in judging what is ethical, more concerned with what one is attempting to do, and whether that attempt falls within our ethical principles. I'm more concerned with that than calling a particular technique ethical or unethical.

Mr. GORE. In other words, you would answer the question by saying you would have to know the purposes for which it was performed?

Mr. GROBSTEIN. Right.

Mr. GORE. There's 1 race horse that has had 16 identical twins from a single embryo. We had testimony last year on livestock genetics. And the emerging trend is apparently to create many replicas of the same embryo and then freeze all but one of them, implant the one representative sample, and determine how well it does as it grows, and then decide later whether or not to take the identical replicas and implant them.

If I asked you the same question about that procedure, I guess you'd give me the same response that it would depend upon the purposes for which it was done?

Mr. GROBSTEIN. Yes, I think so. In the case of the race horses, I could see the possibility that it would make racing less exciting than it has been in the past. [Laughter.]

Mr. GORE. Now, what if one of the purposes was to—and it's very difficult to get into this area, of course, and I hope everyone understands that fact, but I think it's important we do it anyway.

There have been proposals for genetically screening frozen embryos, or embryos outside the body whether they're frozen or not, for genetic characteristics.

At what point would the choice of a particular genetic characteristic justify the making a decision about whether to implant or not to implant?

Mr. GROBSTEIN. Well, I can see that as being conceivably useful and the purposes legitimate.

Mr. GORE. You don't mean a pun there when you say conceivably?

Mr. GROBSTEIN. No; one always has trouble with the true meanings of conceivable.

Mr. GORE. I know, I'm sorry, I couldn't resist all day, excuse me.

Mr. GROBSTEIN. No; I meant the imagining sense.

Mr. GORE. Sure.

Mr. GROBSTEIN. It could very well be that the techniques, for example, of twinning—what you referred to as "cloning," induced cloning, induced twinning—that those could be useful in relation to diagnosis of genetic disease, and could reduce the probabilities of raising individuals with genetic defect. That is, the scenario that has been proposed is that you take an egg that you are considering for transfer; you divide it in two; you freeze one; you then allow the other to continue its development as far as is necessary to make a determination of any genetic defect. If no genetic defect is found, then you unfreeze the other one and use that as the source of the new individual.

On the other hand, if genetic defect is found, then you do not return the second frozen embryo; you, rather, start again to obtain another candidate for transplants.

Mr. GORE. Is that ethical? And please understand that I'm not—I don't want to put you on the spot. And I'm sure that after years of reflection, your views on issues as subtle as these evolve and change—but I'm just asking you for, you know, a rough draft opinion.

Mr. GROBSTEIN. Yeah. Well, you said you didn't want to put me on the spot, but I must admit that I feel on the spot. On the other hand, it's a perfectly legitimate spot to be on.

Again I would say, I can imagine situations in which it would be regarded as ethical to do this, and I can imagine situations in which it would not.

Mr. GORE. Tell me one where you would think it would be ethical.

Mr. GROBSTEIN. I think it would be ethical—I'll use an extreme scenario—if we are faced at some time in the future with a much higher incidence of genetic defect than we are currently faced with in our population, as, for example, might occur following nuclear warfare. Then I think it would be entirely ethical to use procedures of this kind to ensure that we were not propagating in a way that

threatened our continuing survival, because it would increase rather than reduce to the genetic burden that we were carrying.

Am I clear on that? What I'm saying is that if the problem of genetic defect were even more serious than it currently is, which it would be likely to be if we were—if the population was exposed to excessive radiation—then it would be entirely ethical for us to use these procedures in an effort to return ourselves to at least a survivable genetic state.

Mr. GORE. Well, without using the example of a nuclear war, if because of medical advances, genetic—what we regard as genetic defects—were passed along to future generations more commonly, and the incidence of genetic defects increased in the general population, as there is some evidence that it is, would you say that example would also justify such a procedure?

Mr. GROBSTEIN. Yes, I would say that in any situation—and I used one example of how this might happen, but what you're suggesting is another that might happen, would happen less dramatically and less rapidly—but in any situation in which it became imperative for the survival of the species to reduce genetic defect, then I think it would be entirely ethical to use the procedures that we were talking about, in an effort to do so.

Mr. GORE. Who would define the acceptable limits of the definition of "genetic defect," and which defects would justify such a decision?

Mr. GROBSTEIN. I think this is the kind of matter that a deliberative commission such as we're talking about would give attention to.

Mr. GORE. Yeah. Clearly, one threshold question, which causes some people to just really shy away from this whole subject and this whole area, is the question of what our view of the embryo, or cytotblast, or whatever you want to—at different stages—what is our view of its rights, and dignity, and place, in our society. Some people shy away from that question because it is so similar to the painful questions our society has wrestled during the abortion debate. But I think it ought to be clearly recognized—we ought to look it in the eye as one of the threshold and central questions involved in this debate. Would you agree with that?

Mr. GROBSTEIN. Yes; I would say that it is becoming increasingly clear that we can no longer shy away from that issue. I think, again, that is one of the issues that I would hope this deliberative commission would take up. I would also hope that we could take it up in a fresh way, uncomplicated by some of the rigidities that have developed with respect to the abortion matter. And that in finding a fresh approach to that issue, we might even perhaps relax some of the rigidity in the discussion of abortion.

I think that this is now a central matter for consideration. How do we—how should we treat the embryo in its various stages, given the fact that we now have decisions to make about it at times that we're—that are unprecedented, were never faced before. The kinds of decisions, the stages at which we now have to make decisions, are unprecedented; and we have very little guidance from our traditions. We must confront this as a new issue, and we must think in new, imaginative ways.

Mr. GORE. Well, while there are close similarities, there are also some differences in the way that question arises in this context. And in addition, there are a whole series of other ethical dilemmas and problems beyond that one that's similar to the abortion question.

One of the differences is that in this case the embryos are intentionally created in every case. And the decision as to how to behave toward them can be made before the decision to create them. And that, I think, puts a slightly different cast on the issue as well.

Would you agree with that?

Mr. GROBSTEIN. Yes; and I would emphasize that in this instance the declared purpose of intervening in the development of the embryo is the same purpose as in the natural process of human reproduction. It is for that reason that it does not seem to me to be in any sense unethical. But, on the other hand, in having decided to do this, we have also made it possible for those embryos to be used for other purposes. And it is the other purposes that is a subject of debate and that needs deliberation.

Mr. GORE. OK. Let me call on my colleague, Congressman Durbin.

Mr. DURBIN. Thank you, Mr. Gore. This is fascinating testimony. It probably raises more questions than we'll ever be able to answer in one day, I'm certain.

Interesting to me is we asked you what you would consider ethically permissible and you gave the example of the post-nuclear war, but you said you could also think of some instances that would not be ethically permissible. Can you give me a couple of examples of those?

Mr. GROBSTEIN. Yes; they have appeared in scenarios that have been publicly discussed. Certainly if the effort here, or the purpose, were the aggrandizement of some one individual who, whether for egotistical reasons, or political reasons, felt that it was important to have replicas of himself or herself, I would regard that as questionable, certainly, ethically, not nearly as clearly as, perhaps, as the other example that I gave.

But that's one type of use, or purpose, that would seem to me, personally, to be unethical.

Mr. DURBIN. It leaves a wide, middle ground, doesn't it, between the survival of the species and the matter of self-flattery, and self-aggrandizement?

Mr. GROBSTEIN. Yes, I would say so. And we're talking here about extremes and, undoubtedly, the middle area is the one that would need most attention.

Mr. DURBIN. Tell me, if you will, what kind of—as we talked about some of the dilemmas, you know, getting close to the questions we may never be able to answer about the exact moment life begins, and so forth—when you talk about intervention and the development of the human embryo, for example, is there a point where you could come to a conclusion that the efforts have been a failure and the ultimate human to be born from this process will have some terrible defect and then be faced with the dilemma as to whether to allow this to continue?

Mr. GROBSTEIN. It is certainly possible to imagine such a limit, I guess. But we're facing is the definition of human now. I think that

most people are persuaded that human beings, in some sense, ought not to have their lives terminated, ought not to be subject to suffering, and so on. But one can certainly imagine situations in which individuals who are biologically human might be questioned as to their humanness in a social and ethical sense.

I think we will and, as a matter of fact, already confront such issues, certainly the end of life. So we will have to deal with that. They are very difficult issues. I think, myself, when we clarify them and achieve, at least, some degree of consensus, we will find it easier to solve some of the problems that are at the moment contentious, and we may also find it easier to live with ourselves.

Mr. DURBIN. How does that apply, though, to what you're doing, and the decisions that have to be made when you're trying to differentiate between this biological humanity and the social humanity, when you're making—trying to look into the future and decide whether this effort, this intervention in the human embryo, is ultimately going to result in a person, a human being, that could live albeit perhaps with some problems, or a human being less than perfect? How do you go about making that decision, and what role should Government play or not play?

Mr. GROBSTEIN. Well, there are several questions there, and even in isolation they are difficult questions; and when you put them all together, they become extremely formidable. I would say with respect to the last one, that is, what role Government should play, I think we're illustrating what role Government should play right now. I'd certainly think that Government should take the lead in encouraging and facilitating discussion of these matters. It should provide the leadership necessary to establish that these are very important matters for everybody, and that everybody ought to participate in the discussion of them.

I am less certain about what Government should do in directly intervening in policy terms, and statutory terms, and legal terms. There, again, I think it depends on the particular issue. We certainly are accustomed to having Government intervene in matters of life, and death, murder, and punishment, and so on.

But whether Government should intervene in matters at the beginning of life and the decisions about if we can influence the future of an embryo, whether Government should say the direction in which that influence should be exerted, I have my doubts. I think that is a matter more for decision in the private sphere and ranging on down to the smaller units of society—the family, the married couple, the individual.

Mr. DURBIN. I would say that we've raised some major issues here for certain. And the mention of you of the crime of murder brings the whole question right to a point: when are you taking life—not by natural means, but by intervention, whatever it might be, biological, medical, otherwise.

Thank you, Mr. Chairman.

Mr. GORE. Let me just ask one more question and then, although we could talk with you all day and learn a lot from it, because we have so many other distinguished witnesses here, well then we'll move on.

One of the related dilemmas is that—is what do you do with the extra fertilized embryos, the extra embryos created during these

procedures. The Louise Brown birth was preceded by 200 embryos that were discarded for various reasons. And it is now routine—almost routine—in the IVF procedure to discard several embryos other than the one that is chosen for implantation.

Our next panel will correct me if I'm wrong on any of this—but one of the ethical questions is, what do you do with those that are created in addition to the one that's implanted? Do you have any rough draft opinions on that?

Mr. GROBSTEIN. Obviously, that question is more or less serious depending upon how one sees the status of the embryo at that point.

Mr. GORE. Yeah. It's that threshold question again.

Mr. GROBSTEIN. That's right. A number of things have been done which I think are more tactical than strategic, so to speak, in an attempt to deal with that question; that is, one thing that is done is to try to avoid having any surplus embryos—

Mr. GORE. Yeah.

Mr. GROBSTEIN [continuing]. And then you don't have to face the question.

Another one is if you have surplus embryos, then you freeze them. By freezing them and putting them in what one hopes is a state of suspended animation, you postpone the decision. Obviously, sooner or later, the matter will have to be confronted.

The catch-22 situation in Melbourne, where two embryos are frozen; the professionals who are responsible for that say that the procedure they used is not one that has their greatest confidence in terms of the subsequent viability of those embryos and, therefore, the likelihood of their ever transferring them to find out whether or not they will live, I think is very low. Nonetheless, they don't feel they can throw them away.

Mr. GORE. If I may interject without breaking your line of thought there—the Warnock Commission recommended, and one of its recommendations was that the length of time cryopreservation could continue, assuming that the science advances to this stage, as it surely will, that they couldn't be kept longer than the fertile life of the donor. Does that seem like a commonsense limit there to establish?

Mr. GROBSTEIN. Yes; if one's purpose is to see to it that frozen embryos are only used in the pursuit of the initial purpose, which is to allow a particular couple to have an offspring.

Mr. GORE. Yeah.

Mr. GROBSTEIN. Then it makes sense as soon as it's no longer, or either desirable, or possible, to return it for that purpose, then you no longer have that purpose. But the question is what do you do next? And if your initial concern is that the embryo, frozen or otherwise, is already entitled to the full status of a person, then you still are faced with are you entitled at any point to fail to give it the opportunity to develop. And, obviously, if the donor no longer wants it, and you want it to develop, then you're going to have to find some other recipient, and then you face the ethical dilemma of transfer to another woman—the fact that you're having the genetic motherhood separated from the gestational motherhood. So that you're in a—as I say, it's a catch-22 situation.

Now, I will say that looking at this scientifically, I think this particular issue is a bit of a tempest in the teapot, because it—

Mr. GORE. What do you mean, which one, the one—of what to do with the extra embryos?

Mr. GROBSTEIN. Yeah; in the early stage, say, an eight-cell stage, scientifically we would say that although genetically that is an individual, a human individual, it is genetically so only because developmentally it is still not established as a second individual—as we were talking before, you can make it into two or more individuals; so it is not yet developmentally an individual.

Mr. GORE. Of course, when, if—I mean, even that definition would change rather quickly if genetic—if we learned how to turn the switches on and off, then you and I would fit—wouldn't fit the definition of a human being, because we—after that scientific threshold was crossed, true, a cloning would be possible. So, I mean, it's a change in environment.

Mr. GROBSTEIN. But that would confer only on a nucleus capability of going on, the rest of us that we normally think of as you and I would still remain mortal, and we would go in our time.

Mr. GORE. All right. We could go on and on with this, but we're going to channel it into particular directions because we've got some distinguished witnesses that are following you. Dr. Grobstein, thank you for getting us off to such a good start. We appreciate it very much.

Mr. GROBSTEIN. Thank you very much.

Mr. GORE. Let me call our first panel which is made up of two people. First of all, Dr. Howard Jones, director of the Jones Institute for Reproductive Medicine at Eastern Virginia Medical School in Norfolk, VA, and Dr. Gary D. Hodgen, science director for the Jones Institute in the Department of Obstetrics and Gynecology at Eastern Virginia Medical School in Norfolk.

We are delighted to have you both here; if you all could come on up to the witness table. It's an honor to have you both. Without objection, your prepared texts will be included in full in the record at this point. If you care to summarize any portion of it or depart from it on the basis of what you've heard already this morning, you're certainly free to do so. We are going to begin with you, Dr. Jones, and then to Dr. Hodgen. And, Dr. Jones, welcome, and please proceed.

STATEMENTS OF HOWARD W. JONES, JR., M.D., DIRECTOR, THE JONES INSTITUTE FOR REPRODUCTIVE MEDICINE, EASTERN VIRGINIA MEDICAL SCHOOL, NORFOLK, VA, AND GARY D. HODGEN, SCIENTIFIC DIRECTOR, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, JONES INSTITUTE FOR REPRODUCTIVE MEDICINE, NORFOLK, VA

Dr. JONES. Thank you very much.

Congressman Gore and distinguished members of the subcommittee:

First of all, let me thank you again for the opportunity to talk about in vitro fertilization. I feel that I also speak for the 2½ million couples in the United States who are involuntarily infertile

with a condition which cannot be corrected by conventional means, but which can be corrected by in vitro fertilization.

Since the first child was born, as Mr. Gore said in his opening statement, there are probably in excess of 700 couples in the world who have had their infertility problem solved by in vitro fertilization.

In vitro fertilization has been accepted as a standard method of therapy by the American Fertility Society, representing some 8,000 specialists in infertility. And guidelines, both operational and ethical, have been adopted by the Fertility Society and by the American College of Obstetricians and Gynecologists, representing almost 25,000 specialists.

As requested, I will confine my remarks to the scientific aspects of the program. Before describing these, it might be useful to review a few facts of normal reproduction. May we try the first slide.

[Slide.]

Dr. JONES. Each month during the reproductive cycle, a single egg is matured in the ovary, and at about the 14th day is liberated from the ovary by a process called ovulation. And we see here a diagram of the uterus and the two ovaries, the white structures, together with the two fallopian tubes. The egg liberated at about the 14th day of the menstrual cycle—counting day 1 as the day of bleeding—is then picked up by the fallopian tubes, one or the other of the tubes, and is fertilized in the tubes by sperm deposited in the vagina and which have migrated into the fallopian tube. The transit of the fallopian tube of the first unfertilized and subsequently fertilized egg takes 5 or 6 days.

Many disease conditions affect this process. As an example, both of the tubes shown there might need to be removed surgically for some disease, such as bilateral ectopic pregnancies. But there are many other difficulties which could interfere with the process just described.

We can have the slide off now.

It must be emphasized that normal human reproduction is astonishingly inefficient. Any couple desiring pregnancy and normally exposed, will achieve pregnancy in any one menstrual cycle less than 25 percent of the time.

To put it another way, among those who eventually become pregnant, exposure to pregnancy for 3 months is required for 50 percent of all those who eventually will become pregnant, will in fact do so.

The reason that 85 percent of all couples eventually have children is simply that the process can be repeated 12 times each year.

As mentioned above, for many problems of infertility, in vitro fertilization offers a solution. In this process, one or more mature eggs are removed from the ovary by aspiration. The egg is given an opportunity to be fertilized by the sperm of the husband in the laboratory in a plastic dish. At one time this took place in glass, Latin, in vitro, hence, the name of the procedure. After insemination, fertilization, and for a period of up to 72 hours, the fertilized egg, now technically known as a conceptus, is transferred to the uterus of the donor with the hope that pregnancy will occur.

There are inefficiencies at each step of the process. By current techniques, it is now possible to obtain one or more fertilized eggs approximately 95 percent of the time.

The likelihood of successful fertilization and development of each of the fertilizable eggs is also quite high. This means that of all patients from whom an attempt to aspirate eggs is made, a transfer into the uterus of an apparently normally developing conceptus will occur over 85 percent of the time.

The greatest inefficiency is revealed after the transfer process. When only one fertilized mature egg is transferred, the pregnancy rate is about 20 percent in our experience. While this rate approaches that of normal, it is certainly not equal to it and in order to improve the rate a great deal of effort has been devoted to recruiting more than one fertilizable egg per cycle by stimulating patients with suitable drugs and hormones which have been in use for many years to treat patients who do not ovulate spontaneously at all. This approach has been very successful.

With the transfer of two mature fertilized eggs, the pregnancy rate is about 28 percent. With the transfer of three, it is 38 percent, in our experience. The expectancy of pregnancy with the transfer of more than three eggs has not been definitely determined because the number of patients is quite small. Nevertheless, it can be seen that with the transfer of two or three fertilized mature eggs, the pregnancy rate not only approaches but now even exceeds the expectancy of pregnancy for normal human reproduction in any one cycle.

It is likely that further refinement will increase the number of available fertilized eggs. However, the transfer of more than one fertilized egg risks multiple pregnancies. While twins are medically satisfactory and socially acceptable and, indeed, often desired by infertile couples, multiple pregnancies above two do present obstetrical problems and certainly equally difficult social and family problems.

At the present state of knowledge, there is no known method of examination which allows us to determine prior to transfer which of the fertilized eggs will perish and which will produce a viable pregnancy.

As we look at these eggs through the high power of the microscope, we are probably looking at, but unable to recognize, the factors responsible for the peculiar inefficiency of human reproduction. For the first time in human endeavor, there is an opportunity to study in detail this basic facet of reproductive biology.

The gynecologist and his patient face a dilemma. On one hand, to expose too few eggs to fertilization risks failure; to expose too many, risks multiple pregnancies.

While there are numerous problems which need attention, I will cite again two scientific opportunities which this new technique has made available.

First, there is need to study the details of the inefficiency of human reproduction. A solution to this problem would provide a quantum leap in improving fertility where that is important; and on the other hand, in controlling fertility where that is appropriate.

Second, there is a need to study a method of preservation of the egg, both unfertilized and fertilized, in order to improve the efficiency of in vitro fertilization by making it possible to repeat the transfer process for a given patient in subsequent cycles in event the first transfer were not successful.

It has not been possible to secure adequate funding to actively pursue these research opportunities in the United States because of the policy of the National Institutes of Health, which will not accept grant requests in this area. The details of this policy are, I am sure, well known to members of this committee.

I would like to express the hope that in due course this policy could be reevaluated so that the United States would be in a position to offer its citizens the benefits of the latest medical developments.

So far, my remarks have been directed toward what might be referred to as basic in vitro fertilization. There are, nevertheless, variations which are scientifically possible.

First involves the use of donor sperm. The indication for this in an in vitro program would be quite unusual but nevertheless possible, and occurs if the female has some condition requiring in vitro fertilization and her husband has inadequate sperm. Donor sperm where the female is normal have been used for many years for the treatment of male infertility and the use of this technique in in vitro fertilization is certainly scientifically possible.

It happens that we have not used this technique in our own program but it may have been used in other American programs. Although I have no personal knowledge of this, it has certainly been used extensively in programs in other countries.

Second, there are women who, for a variety of reasons, cannot produce an egg. As, for example, individuals who are born without ovaries. For these women, a donor egg is a viable scientific option. The scientific feasibility of this has been demonstrated by my colleague, Dr. Hodgen, in the primate, and there is, I believe, one such successful human experience at the Queen Victoria Medical Center in Australia.

Thus, it is clear that from a scientific point of view, this variation is possible. Our own Institutional Review Committee has approved such a program and the necessary consent form, but to this moment this program has not yet been implemented.

The preservation of an egg, unfertilized or fertilized, with subsequent use in the event pregnancy does not occur in the first cycle has been referred to above. To the present time, it has not been possible to preserve, by freezing or any other method, an unfertilized human egg. Indeed, it has not been possible to preserve any mammalian egg and have it retain viability. This represents an important area of investigation. It has been possible, as we've already discussed, cryopreserved fertilized eggs at the four, eight, or perhaps even later cell stage.

The feasibility of this procedure in the human has been demonstrated. The process has considerable medical attractiveness in that it would make possible repeated transfers following a single harvest of multiple eggs.

Clearly, the preservation of fertilized eggs could lead to troublesome social problems, as recently illustrated by the experience of the unclaimed fertilized eggs in Australia.

It should be emphasized that the American Fertility Society, in January of this year, adopted and published guidelines covering these various options; and had the guidelines been in effect in Australia, the problem would not have occurred.

While I have emphasized some of the research opportunities provided by basic in vitro fertilization and have pointed out the scientific variance which are possible, I would conclude the summary of my statement by emphasizing that the main purpose of any program of in vitro fertilization is a solution to the problem of infertility—it works.

And, Mr. Chairman, if I may ask some Washington mothers of in vitro fertilization to stand, I would like them to do so. They happen to arrive today; I didn't know they were here, but I saw them, and perhaps, if it would be agreeable——

Mr. GORE. Oh, surely.

Dr. JONES. All right, mothers. [Standing.]

Mr. GORE. Now, remain standing for just a moment if you would. These are all women who have had children as a result of in vitro fertilization. Well, wonderful. We are delighted that you could attend here today. And, thank you very much.

Dr. JONES. I don't think Mrs. Brooks will mind my revealing the fact that she happens to be the oldest mother in the world of in vitro fertilization.

If you care to ask her her age, you may risk it. [Laughter.]

Mr. GORE. You recommend that I do that?

Dr. JONES. I think it's all right.

Mr. GORE. Mrs. Brooks, tell me your full name if you would.

Mrs. BROOKS. I am Barbara Brooks. And I think it has already been posed by Dr. Howard, I'm 41.

Mr. GORE. Congratulations to you. Congratulations to you all.

Dr. JONES. Well, its greatest rewards are in its children.

[Slide.]

Dr. JONES. And the photograph that we just showed there, which seems to—the next one—simply shows the rewards that are in this process, not only in the happy children, but in the happy families.

I thank you for your attention.

[The prepared statement of Dr. Jones follows:]

TESTIMONY
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES
August 8, 1984

Howard W. Jones, Jr., M. D.

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Professor Emeritus of Gynecology and Obstetrics
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It may be estimated that there are approximately 2.5 million couples in the United States who are involuntarily infertile due to conditions which are not treatable except by in vitro fertilization or a related technique. The technique of in vitro fertilization was first successful in Oldham, England in 1978 in a program devised by Robert Edwards and Patrick Steptoe. The first child was born in the United States in our program at Norfolk, Virginia in 1981. We have recently delivered our 64th normal child which happens to make our program not only the first but also the most productive program in the United States. To my knowledge, there are now many other programs in the United States and in addition to those in England, there are programs in Australia, France, Belgim, The Netherlands, West Germany, Spain, Denmark, Sweden, Finland, Isrrel, Canada, Mexico, Columbia, Chile, Japan, and perhaps elsewhere.

As of April 1984, 590 live births had been documented worldwide.

Thus, in vitro fertilization has shown that it can be the solution to problems of infertility not solvable by other means. Furthermore, the spread of the technique in the United States and worldwide reflects the demand for its benefits.

In the United States, the two major professional organizations, the American Fertility Society composed of over 8,000 specialists in infertility, and the American College of Obstetricians and Gynecologists composed of about 25,000 specialists in obstetrics and gynecology have adopted resolutions declaring in vitro fertilization to be standard clinical practice (attachments A,B).

In addition, the American Fertility Society has published minimal standards for programs of in vitro fertilization in the United States (attachment C), as well as ethical guidelines (attachment D).

Thus, there is every reason to think that programs of in vitro fertilization will continue to proliferate nationally and internationally.

Before briefly describing the technique of in vitro fertilization, it might be useful to review a few facts of normal human reproduction.

Each month during the reproductive cycle of the human female, a single egg is matured in the ovary and at about the 14th day of the menstrual cycle (counting day 1 the day of the first menstrual bleeding) the egg is liberated from the ovary in a process referred to as ovulation. The egg is picked up by one of the two fallopian tubes and fertilized within the fallopian tube probably within 24 hours, or shorter, after ovulation. Fertilization occurs from sperm which have been deposited in the vagina of the human female and which have moved from there through the uterus into the fallopian tube where they meet the egg. It normally takes 5 or 6 days for the egg during its unfertilized and later fertilized state to traverse the fallopian tube and be deposited in the uterus.

Many disease conditions affect this process. For example, both fallopian tubes may require surgical removal due to ectopic pregnancies. This is but one example of the numerous conditions which can interfere with normal reproduction. The example, however, illustrates one of the problems that can be nicely solved by in vitro fertilization.

It needs to be emphasized that normal human reproduction is astonishingly inefficient. Among couples who eventually become pregnant and who are anxious to achieve pregnancy during any one month of exposure a viable pregnancy is likely in no more than 20 or 25% of the months. To put it another way, among those who eventually become pregnant, exposure to pregnancy for 3 months is required before 50% of all those who will become pregnant actually do so. The reason that most couples who wish to have a family eventually do so is simply because there are 12 opportunities each year for this process to be repeated.

For many problems of infertility, as in the example referred to above, in vitro fertilization offers a solution. In this process, one or more mature eggs are removed from the ovary by aspiration of an egg immediately prior to the time that it would be normally ovulated. The egg is then given an opportunity to be fertilized in the laboratory, at one time in a glass container, i.e. in vitro, hence, the name of the process, by the sperm of the husband. After fertilization and development for a period of 48 to 72 hours after insemination, a fertilized egg, now technically known as a conceptus, is transferred to the uterus of the donor of the egg.

There are inefficiencies in each step of the process. By current techniques, it is now possible to obtain one or more fertilizable eggs from the female over 95% of the time. The likelihood of successful fertilization and development of each of the fertilizable eggs is also quite high. This means that of all patients from whom an attempt to aspirate eggs is made, transfers into the uteri of those patients of what seem to be normally dividing eggs occur well over 80% of the time. The

greatest inefficiency occurs in the establishment of pregnancy. When only one mature egg is transferred, the pregnancy rate is about 20% in our experience. While this rate approaches that of normal, it is certainly not equal to it and in order to improve the rate a great deal of effort has been devoted to recruiting more than one fertilizable egg per cycle by stimulating patients with suitable drugs and hormones which have been in use for some years to treat patients who do not ovulate at all. This approach has been quite successful. With the transfer of 2 mature fertilized eggs, the pregnancy rate is 28% and with the transfer of 3, it is 38% in our experience. The expectancy of pregnancy with the transfer of more than 3 eggs has not been definitely determined as the number of patients is too small. Nevertheless, it can be seen that with the transfer of 2 or 3 fertilized mature eggs, the pregnancy rate not only approaches but even exceeds the expectancy of pregnancy for normal human reproduction.

It is likely that further refinement will increase the number of available fertilizable eggs. However, the transfer of more than one fertilized egg risks multiple pregnancies. While twins are medically satisfactory and socially acceptable and indeed often desired by infertile couples, multiple pregnancies above 2 present obstetrical problems and equally difficult social problems.

At the present state of our knowledge, there is no known method of examination which will now enable us to determine prior to transfer which of the fertilized eggs will perish and which will produce a viable pregnancy. As we look at these eggs through the high power of the microscope, we are probably looking at but unable to recognize the factors

responsible for inefficiency of human reproduction. For the first time in human endeavor, there is an opportunity to study in detail this basic facet of reproductive physiology.

The gynecologist and his patient face a serious dilemma. On one hand, to expose too few eggs to fertilization risks failure and if one transfers all fertilized eggs, to expose too many, risks multiple pregnancies.

Thus, the process of in vitro fertilization has pinpointed several scientific problems the solution of which would vastly increase our understanding of human reproduction in general and more directly help to solve the problem of infertility of countless couples.

While there are numerous problems which need attention, I shall confine my remarks to only two as examples of the scientific opportunities which this new technique has made available.

1. There is need to study the details of the inefficiency of human reproduction.
2. There is need to study the preservation of eggs both unfertilized and fertilized.

The benefits to the solution of these problems are great.

If we knew why some fertilized eggs were viable and some were not, there would be a quantum leap in improving fertility where that was appropriate or in controlling fertility where that was appropriate.

The preservation, and with present techniques this means cryopreservation, of eggs would improve the efficiency of in vitro fertilization by making it possible to repeat the transfer process in a given

patient in subsequent cycles in event the first transfer was not successful. It has not been possible to secure adequate funding to actively pursue these research opportunities in the United States because of the restrictive policies of The National Institutes of Health toward funding research in this area. The details of that policy are, I am sure, familiar to the members of this committee. I would like to express the hope that these restrictions would be lifted in due course so that the United States would be in a position to do those things which are necessary to offer its citizens the latest medical developments.

So far, except for a brief reference to cryopreservation, my remarks have been directed toward what might be referred to as basic in vitro fertilization. There nevertheless exists a variety of variations which are scientifically possible.

The first of these involves the use of donor sperm. The indication for this in in vitro fertilization would be quite unusual but nevertheless is possible and occurs if the female has some condition requiring in vitro fertilization and her husband has inadequate sperm. Donor sperm with a normal female have been used for many years quite successfully as a treatment for male infertility and the use of this technique in in vitro fertilization is certainly scientifically possible. We have not used this technique to date in our own program. It may have been used in some American programs. It has certainly been used in the programs in Australia and elsewhere.

There are some women who for a variety of reasons cannot produce an egg but whose husbands are quite normally fertile. For these women, a donor egg is a viable scientific option. The scientific feasibility of

this has been demonstrated by my colleague, Dr. Hodgen, in the primate and there is, I believe, one such successful human experience at the Queen Victoria Medical Center in Australia. Thus, it is clear that from a scientific point of view, this particular variation is a scientific possibility. Our own Institutional Review Committee has reviewed and approved a program and the necessary consent forms to proceed with this method of therapy.

The use of cryopreservation was referred to above. Up until the present time, it has not been possible to cryopreserve an unfertilized human egg. Indeed, it has not been possible to cryopreserve any mammalian egg and have it retain viability. This represents an important area of investigation. It is probably a solvable problem in view of the fact that the difficulty revolves around the fact that the egg is the largest cell in the body and that cryopreservation is unsuccessful due to the formation of ice crystals within the egg itself. It has been possible to successfully cryopreserve fertilized eggs at the 4 or 8 cell, or later stage in a number of species and an Australian group has demonstrated its feasibility in the human. The efficiency of this process is not at the present time all that it might be and this fact is probably related in some measure to the inability to determine prior to cryopreservation the potential viability of the individual fertilized egg. This presents an important area of investigation. The process has considerable medical attractiveness in that it would make possible repeated transfers following a single harvest of multiple eggs. . It should be added that cryopreserved concepti if the infertility problem of the original donors has been solved become available for adoption. From

a biological point of view, there is no reason why this is not completely compatible although to my knowledge in the human this particular variation has not been accomplished.

The medical attractiveness of cryopreservation or perhaps some other method of preservation is such that the developments in this field must be seriously considered by anyone who wishes to provide the very best for the patient.

I might add that the guidelines of the American Fertility Society (attachment D) provide for various contingencies in these procedures and if followed would circumvent the problem illustrated by the cryopreserved orphaned concepti in Australia.

Cryopreservation in addition to the scientific problems remaining to be solved presents at least for some people ethical problems which will be considered by another panel

Thus, in vitro fertilization and its variants offer a unique solution to problems which otherwise have been unsolvable in the field of infertility and from a scientific point of view has provided opportunities which if developed with understanding and skill will provide great benefits for society in general.



THE AMERICAN FERTILITY SOCIETY

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NEWS

1608 13th Avenue South
Birmingham, Alabama 35256

(ATTACHMENT A)

LAS VEGAS - The following resolution was passed by the Board of Directors of The American Fertility Society at its annual meeting here March 20-24, 1982.

"In view of the current rate of success in programs of in-vitro fertilization it is the sense of the Board of Directors of The American Fertility Society that in appropriately staffed and equipped institutions that have demonstrated proficiency and success, in-vitro fertilization must now be recognized as the acceptable treatment for achieving pregnancy for couples whose wives have absent or irreparably damaged fallopian tubes."

The following motion was passed unanimously by the members of The American Fertility Society at their annual meeting. The American Fertility Society is composed of over 7,000 members who are actively involved in research, and therapy of involuntary infertility.

"Previously an advisory committee formed by the Department of Health and Human Services has reported favorably on the ethics of in-vitro fertilization. To date no action has been taken by Health and Human Services on this report.

In view of recent studies, the members of The American Fertility Society believe the Department of Health and Human Services should re-establish research grants to further improvements in techniques for in-vitro fertilization and embryo transfer."

ACOG releases guidelines for In vitro fertilization clinics

In vitro fertilization clinics should be directed by a specialist in reproductive endocrinology and should have on staff a surgeon skilled in oocyte aspiration, a specialist in male reproductive physiology and semenology, and a specialist in tissue culture, according to guidelines recently released by ACOG.

Any facility carrying out the procedure should be able to provide ultrasonography, laparoscopic retrieval, anesthesia, and laboratory services 24 hours a day.

Howard Jones, MD, head of the Eastern Virginia Medical School program that three years ago delivered the first American baby conceived by in vitro fertiliza-



tion, presented the guidelines during a press conference at the Annual Clinical Meeting.

Dr. Jones noted that the guidelines are "preventive medicine." There are about 60 in vitro fertilization clinics in the U.S. now, he said, and he expects more to open soon. "We don't believe there are any operating under suboptimal conditions, but are putting forth standards as a precautionary measure."

Dr. Jones estimated that 1,000 couples sought help at in vitro clinics in the U.S. last year. He said that there are probably 2% million infertile couples in the nation who could be helped through the procedure. Though costs vary from clinic to clinic, his facility charges \$4,000 for each attempt at conception through in vitro fertilization.

The guidelines, which were drawn up by ACOG's Committee on Gynecologic Practice and are backed by the American Fertility Society, follow.

Background

The technique for extracorporeal fertilization commonly known as in vitro fertilization and embryo placement (IVF-EP) was originally evaluated in the early 1970s. The first studies were carried out chiefly in England by a group of investigators headed by Dr. Robert Edwards and Dr. Patrick Steptoe (1). In 1978, the first live human offspring resulting from IVF-EP was born in England. During 1978-80 pro-

grams began in Australia in two different universities, both of which reported successful live births in 1980 and 1981 (2-4). In 1980, the first in vitro fertilization program in the United States was established at Eastern Virginia Medical School, which delivered its first live healthy offspring in December 1981 (5). The second program established in the United States, at the University of Southern California, resulted in a live birth in June 1982 (6,7). In the past year, there has been a marked increase in the number of programs being established in the United States, both in the private sector and at the major university centers.

Originally, IVF-EP was designed for patients with severe tubal disease, although the technique has expanded to include treatment of severe male factor infertility (oligozoospermic male) as well as of couples who have not had an explanation for their infertile state (the so-called idiopathic infertility group). Success rates with these groups have not been established.

Because the number of infertile couples in the United States is increasing, the need for IVF-EP programs is apparent. The main concern right now is determining what qualifications and types of facilities are necessary to provide optimal chances for successful outcome. Ideally, IVF-EP should be performed and managed in a hospital setting. Whether the procedure is carried out in a university research center or in private community hospitals, rigid standards and quality control must be maintained.

Technique

The human IVF-EP process involves several steps. Currently, ovarian hyperstimulation is induced with several different types of medications. Protocols most commonly used are clomiphene citrate in doses ranging from 50-150 mg/day or variable doses of human menopausal gonadotropins (Pergonal) either combined with clomiphene or as a single agent (7,8). This hyperstimulation encourages the development of multiple oocytes, which are recovered by laparoscopy for fertilization in vitro. The use of gonadotropin-releasing hormone may be a future development that could provide a more physiologic ovarian stimulation for multiple follicle development (9).

The response to stimulation is monitored primarily by serum or urinary estradiol measurement. Luteinizing hormone measurements and daily real-time

ultrasound are utilized to determine follicular growth parameters, the number of follicles developing, and the time of ovulation initiation. The results of these determinations are correlated to judge the response to stimulation and the time of follicle maturation.

The laparoscopy for oocyte retrieval is performed under general anesthesia with a specifically designed oocyte collection system. Follicular fluid analysis is performed very rapidly for identification and staging of the maturity of the collected oocytes. It is preferred, but not essential, that an established tissue culture laboratory be near the operating suite. This laboratory is used for oocyte identification, oocyte culturing, sperm washing, and insemination. Over a 40-hour period, oocyte-embryo culturing is performed resulting in the development of the early conceptus. Within 40-48 hours after oocyte collection, the embryo is transferred by transcervical route back into the oocyte donor. This is done without an anesthetic. The patient is then maintained at rest for a variable period of time, usually less than 24 hours, after which she is discharged.

Risks

Each step in the human IVF-EP procedure has potential risks. The use of stimulatory drugs for ovarian hyperstimulation carries a slight risk of ovarian hyperstimulation syndrome. The IVF-EP patients usually have one of a variety of problems related to the pelvic cavity, such as endometriosis, tubal occlusion, or pelvic inflammations, that has caused the infertility. Because this is a high-risk population of patients, a gynecologic laparoscopist with superior skill is required to minimize the risks involved in oocyte collection.

Initially, in vitro culturing of oocytes was thought possibly to increase the risk of congenital anomalies in the offspring. As of the end of 1983 more than 250 IVF-EP babies had been born worldwide, with two congenital anomalies seen. Both infants had congenital cardiac defects not thought to be associated with the IVF-EP process itself. There have been three known trisomic pregnancies, two resulted in abortion in France, the third was a tubal pregnancy that was removed in Australia. Amniocentesis should be considered for IVF-EP patients, especially those over the age of 35.

Benefits

The IVF-EP pregnancy rate has shown a steady increase since the first IVF-EP pregnancy occurred in England.

In 1983 in the United States, using multiple oocyte transfer, pregnancy rates ranged from 20-30% per transferred cycle (10,11). In Australia and England the pregnancy success is about the same as that in the United States.

Ethical Considerations

Any couple entering the IVF-EP process must undergo extensive counseling and discussion of the procedure, with risks and benefits described, before beginning an in vitro cycle. Research and treatment involving IVF-EP raise many questions of ethical importance now being widely debated by the public as well as within the medical and legal communities. A discussion of these issues will be made available by the College in the near future.

Requirements for IVF-EP Programs

Whether done in a private community hospital or university-based medical center, each type of procedure performed should be subject to review and evaluation. Every group initiating a program should have all aspects of the program approved by an institutional review committee or its equivalent. Accurate data keeping and record collection should be provided within the in vitro program, and these records should be maintained as confidential. All the medical aspects of the treatment cycles should be recorded, as should the success or failure of oocyte recovery, fertilization, cleavage, conceptus transfer, physical monitoring of fetal growth, pregnancy, and pregnancy outcome. Complications that occur before egg recovery, during laparoscopy, or after egg culturing, or any problems that occur during or after pregnancy, should be recorded.

Personnel Requirements

To assure adequate patient care, expertise in four skill areas is essential for personnel working in an IVF-EP program. These skills may be concentrated in one or two individuals, or may be spread among four or more. The following are necessary:

- A person to direct the program who has the expertise and training required for board certification in reproductive endocrinology, a basic laboratory scientist who has experience in laboratory work, or an embryologist in the human or animal field would not be an acceptable director
- A surgeon with a depth of expertise in operative laparoscopic procedure.

dures and ability and training in oocyte aspiration techniques.

- A PhD or MD experienced in male reproductive physiology, with special competence in semenology.
- An individual, preferably with a doctoral degree, with knowledge and a working experience in tissue culture, gamete maturation, fertilization, and cleavage in human concepti, as well as knowledge of animal systems.

Special Services and Facilities

The physical plant in which IVF-EP will be carried out must contain facilities for the following:

- **Ultrasonography.** Must be available 7 days a week. This can be done through the hospital's radiology department, but more appropriately should be performed by one of the IVF-EP team members.
- **Operating Room.** Facilities necessary for laparoscopic retrieval can be found either in an outpatient surgical center or an inpatient operating theater setup. The availability must be rigidly controlled so that patients can be moved in and out of the operating room on a regular schedule 7 days a week, within a maximum of 24 hours notice.
- **Anesthesia.** Must be available 7 days a week.
- **Laboratory.** The quality of the embryo culture laboratory is very important. The purity of the water and quality of the culture media and their supplement are critical to obtaining viable pregnancies in an IVF-EP program. Rapid hormonal assay systems capable of measuring estradiol and luteinizing hormone must be available 7 days a week. The facility for oocyte-sperm culturing should be close to the operating room, with two-way communication. Necessary equipment varies from laboratory to laboratory, but must include a controlled incubation system, magnification system for identifying oocytes and embryos, and a system to maintain quality control of media preparations from week to week. Most commonly, mouse embryo growth and development rates are used to determine the safe media for use in the human egg system.

Summary

Today in the United States, human IVF-EP is a clinically applicable procedure.

It is no longer considered purely experimental.

IVF-EP requires maintenance of certain standards, which have been outlined here, and thoughtful consideration to ethical issues involved. If done by competent individuals in well-organized centers, this process can benefit a large segment of the infertile population that was heretofore unable to be treated satisfactorily. If the aforementioned guidelines are followed, a program for IVF-EP can be established in a private setting as well as in university-based hospital systems. However, it should be cautioned that the procedure itself is very complex, highly technical, and requires a large backup system of laboratory support and specialized personnel available 7 days a week.

April, 1984

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Minimal standards for programs of in vitro fertilization

American Fertility Society*†

I. General Considerations

Every group initiating a program of in vitro fertilization should have all aspects of the program approved by a properly constituted Institutional Review Committee. The Institutional Review Committee or its equivalent should ensure that a record is kept of all attempts made at securing pregnancies by these techniques. The records should include all medical aspects of the treatment cycles and a record of success or failure with respect to oocyte recovery, fertilization, cleavage, conceptus transfer, biophysical monitoring of fetal growth, pregnancy outcome, and complications. These institutional records, which should be separate from the regular records of the medical institution, should be confidential. Summaries for statistical purposes, including details of any congenital abnormalities among offspring, should be available for correlation.

It is recommended that special attention be given to the emotional needs and the emotional support of these patients.

It is recommended that the director of the program have clinical experience and competence.

In view of the many research opportunities offered by programs of in vitro fertilization, it is urged that all programs be

designed to take advantage of these opportunities.

II. Personnel

Personnel with the following four types of skills are required as a minimum. A single individual may possess one or more of the required skills.

(1) An individual with the experience and training required for board certification in reproductive endocrinology. While individuals with equivalent training and experience are certainly acceptable, board certification clearly indicates that the required skills in reproductive endocrinology have been obtained.

(2) A pelvic reparative surgeon with laparoscopic experience with evidence of specialized training in follicular aspiration.

(3) An individual experienced in male reproduction (andrology) with special competence in semenology.

(4) An individual with knowledge of and practical experience in tissue culture, gamete maturation, fertilization, and early zygote cleavage in human and animal systems.

III. Special Services and Facilities

These services and facilities must be on call on a daily basis with 24-hour availability.

(1) Ultrasonography.

(2) Hormonal assays.

(3) Facilities for follicular aspiration and conceptus transfer.

(4) Anesthesia.

(5) A laboratory for gamete fertilization and conceptus development near the operating room with two-way communication between the laboratory and operating room.

*Report of an ad hoc committee of The American Fertility Society: Howard W. Jones, Jr., M.D., Chairman, Anne Colston Wentz, M.D., Martin M. Quigley, M.D., Richard P. Marrs, M.D., and C. Alvin Paulsen, M.D. Approved by the Board of Directors of The American Fertility Society.

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Special Contributions

(ATTACHMENT D)

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Ethical statement on in vitro fertilization

American Fertility Society*†

- I. In vitro fertilization for infertility not solvable by other means is considered ethical.
- II. It is understood that any couple entering into a program of in vitro fertilization will have discussed and signed a proper consent form covering the various steps in the procedure. It is understood that the gametes and concepti are the property of the donors. The donors therefore have the right to decide at their sole discretion the disposition of these items, provided such disposition is within medical and ethical guidelines as outlined herein.
- III. In the event there are concepti in excess of those required for transfer in the harvest cycle, they may be treated at the option of the couple in accordance with paragraphs IV, V, or VII.
- IV. It is considered ethically acceptable to scientifically examine any conceptus donated for this purpose, provided such examination is carried out prior to the time development has reached the stage when implantation would normally occur. For purposes of this paragraph, 14 days after insemination is considered to be the limit.
- V. Nontransferred concepti should not be allowed to develop in the laboratory more than 14 days and may be disposed of without scientific examination.
- VI. Cryopreservation of concepti for the purpose of subsequent implantation into the female partner is acceptable with certain provisions. The concepti should not be retained in the cryopreserved state for longer than the reproductive life of the female donor. However, the disposition of any unused cryopreserved concepti should be provided for prior to cryopreservation and in accordance with the guidelines of paragraphs IV, V, or VII.
- VII. After the reproductive problem has been resolved to the satisfaction of the donors, it is considered ethically acceptable to donate to another infertile couple nontransferred concepti, provided any claim to any resulting progeny is waived and provided strict anonymity between donors and recipients is assured as in any adoptive procedure.
- VIII. Donor sperm should be looked upon as any other donor insemination technique and should be considered ethical and sound for those males that even with in vitro fertilization cannot fertilize normally.
- IX. Donor oocytes should be considered ethical and sound for those females who have no oocytes or whose oocytes are not available by contemporary techniques.

*Report of an ad hoc committee of The American Fertility Society: Howard W. Jones, Jr., M.D., Chairman, Anne Colston Wentz, M.D., Martin M. Quigley, M.D., Richard F. Morris, M.D., and C. Alvin Paulsen, M.D. Approved by the Board of Directors of The American Fertility Society.

†Reprint requests: The American Fertility Society, 1608 13th Avenue South, Suite 101, Birmingham, Alabama 35256

(5/7/84)

CURRICULUM VITAE

Howard Wilbur Jones, Jr., M. D.

Birth: December 30, 1910, Baltimore, Maryland
 College: A.B., 1931, Amherst College (cum laude)
 Medical School: M.D., 1935, Johns Hopkins University School of Medicine
 Honorary Degree: Dr. Honoris Causis (Cordoba) 1968
 Postgraduate Training: House Officer, Assistant Resident and Resident Gynecologist, Johns Hopkins Hospital, 1937-37, 1947.
 Visiting Gynecologist, Union Memorial Hospital, Bon Secour Hospital and St. Agnes Hospital, Baltimore, Maryland
 Attending Staff, Medical Center Hospitals, Norfolk, Virginia
 Attending Staff, DePaul Hospital, Norfolk, Virginia
 Other Appointments: Co-Editor-in-Chief for Gynecology: Obstetrical and Gynecological Survey, The Williams and Wilkins Company
 National Consultant to the Surgeon General, U.S. Air Force.
 Medical Societies: Baltimore City Medical Society
 Medical and Chirurgical Faculty of Maryland
 American Medical Association
 American Association for Cancer Research
 American College of Obstetricians and Gynecologists
 North American Gynecological Society
 American Gynecological Travel Club
 Society of Pelvic Surgeons
 Sociedad de Obstetricia y Gynecologia de Buenos Aires
 Sociedad de Obstetricia y Gynecologia de Cordoba
 Sociedad Peruana de Obstetricia y Ginecologia
 American Society of Human Genetics
 La Sociedad Chilena de Obstetricia y Ginecologia
 Sociedad Chilena de Endocrinologia
 Sociedad Argentina de Citologia
 Korean Obstetrical and Gynecological Society
 Nigerian Society of Obstetrics and Gynaecology
 American Gynecological Society
 Society of Medical Consultants to the Armed Forces
 Virginia Society of Medicine
 Norfolk Academy of Medicine
 Fertility of Australia (honorary life membership)

- Honors:** Ayerst Lecturer: American Fertility Society
1975
Green-Armytage Lecturer: Royal College of
Obstetricians and Gynecologist
1976
S. Leon Israel Lecturer: Pennsylvania Hospital,
1976
McIlrath Professor, Royal Prince Alfred Hospital,
Sydney, Australia, 1977
Honorary Consultant, Royal Prince Alfred Hospital,
Sydney, Australia
Medal - College de France, 1978
- War Service:** June 1943 to January 1946
Branch Medical Corps, 5th Aux. Surg. Group
Rank on Discharge, Major
Award, Bronze Star
- University
Appointments:** Professor, Gynecology and Obstetrics
Johns Hopkins University School of Medicine, 1967

Acting Chairman, Department of Obstetrics and
Gynecology, 1970-1971, Johns Hopkins School of Medicine

Secretary General, Johns Hopkins Program for
International Education in Gynecology and
Obstetrics, 1974-1977

Professor Emeritus, Gynecology and Obstetrics,
Johns Hopkins University School of Medicine,
1976-1978

Professor, Obstetrics and Gynecology, Eastern
Virginia Medical School, Norfolk, Virginia
1978-
- Clubs:** Grachur Club
Johns Hopkins Club
Gibson Island Club
Hamilton Street Club
- Marriage:** Georgeanna E. Seegar, 1940
M.D. Johns Hopkins University School of Medicine
1936.
- Children:** Three

Mr. GORE. Yes, sir, thank you.

And I think most Americans in the first—I'm not going to get into questions now, we want to go to you—but I'm just going to make a quick comment. I think that a lot of Americans, when first confronted with the in vitro questions, and your program was the first in the United States, and produced the first in vitro child in the United States, and I believe 64 others, if—Is that correct?

Dr. JONES. Now 65.

Mr. GORE. Now 65. I believe that a lot of Americans, when they were first confronted with your achievements and Dr. Steptoe's, and others, wondered, you know, what we're getting into. But then when they realized the great joy and happiness that these families experience as a result of this technology, I think there was an overwhelming conclusion reached that this is a tremendous blessing for the many thousands, and I guess millions, of people who can benefit from the procedure. But difficult questions still remain, and they haven't gone away.

And we'll get to a few of them after we hear from our next witness, Dr. Gary Hodgen—Did I pronounce that right?

Mr. HODGEN. That's right.

Mr. GORE. OK—Science director for the Jones Institute. We are delighted to have you here, Dr. Hodgen, and we invite you to proceed.

Mr. HODGEN. Thank you.

Mr. Gore, distinguished members of the subcommittee.

It's my pleasure to give remarks primarily focused again toward the scientific aspects.

I've divided the presentation into principal areas of focus, the first being the need for infertility treatment. As you see in my summary, and at appendix page marked A, of data presented recently at the May 1984 3d World Congress on in vitro fertilization and embryo transfer, this treatment for infertility is now a proven therapeutic success.

Indeed, since I presented these data to a committee of the National Academy of Sciences, the number of children born as a result of IVF/embryo transfer therapy now surely exceeds 700, with perhaps as many as 300 ongoing pregnancies.

Although an exact count is not available, approximately 200 in vitro programs have been initiated worldwide, and about 50 of those perhaps in the United States at various medical centers and clinics.

Among established programs where this treatment is successful in 25 to 35 percent of the treatment cycles, patient demand for this help is incessant; there are long waiting lines despite substantial increases in the number of patients being treated by the new procedure.

More importantly, the nature of reproductive health problems being confronted through this technology is becoming increasingly complex. That is, the in vitro fertilization/embryo transfer technique or procedure is no longer a naive experimental or single-minded approach to curing the problem of irreparably blocked fallopian tubes.

The number of caveat procedures, both those already developed and others anticipated, demonstrates our collective capacity to

apply this new knowledge for the resolution of an ever broadening spectrum of causes of reproductive failure.

For example, new techniques are providing treatment opportunities in vitro for infertile men who have too few or qualitatively diminished sperms.

There is an increasing demand for donor eggs or embryos for couples unable to provide their own because of ovarian failure or obvious risks of heritable disease. For them, this new opportunity brings the special attractiveness of experiencing the life-giving act of pregnancy and delivery as a part of the parenting process.

Finally, it is important not to forget the need to improve upon present levels of effectiveness and safety in the IVF/embryo transfer therapy.

As you have perceived from the media and other sources, these new reproductive technologies are dynamic, and undergoing refinement and reapplication as extension of previous successful treatments.

We ask: What propels this process? Foremost, it's the demand of the patient.

Let's turn our attention now to the scientific process that works alongside these medical achievements. Typically, IVF/embryo transfer therapy necessitates the coordinate scientific, medical and technical expertises uniquely available in a specialized team very much working together. Often these teams are comprised of 15 to 25 persons having highly specialized knowledges and instrumentations. Moreover, rarely is the scientific process remote from the physician-scientist education process and patient care.

Accordingly, medical centers that have directed a major allocation of personnel, budgetary and spatial resources toward solution of these problems in reproductive health have provided the most scientific impetus for the IVF/embryo transfer research.

However, relevant and timely data are also contributed by private IVF/embryo transfer clinics, groups doing research but not directly associated with patient care, and very importantly, corporate research which can provide improved medications, media, and specialized devices.

Often the initial feasibility of these new approaches in human in vitro fertilization/embryo transfer are first demonstrated in laboratory animals or, as mentioned earlier this morning, the agricultural animal industry. These interrelationships are spontaneous and naturally operative irrespective of more provincial primary goals.

The next area that I turn my attention to are principal research objectives, and I have listed six here as examples. And by no means do I infer this as a complete or thorough listing, but only to make the points.

In the terms of short term objective, the freezing and storage and thawing of human embryos for subsequent transfer to infertile women is already a practical reality. However, a safe and reliable method of freezing and thawing human eggs unfertilized has not been reported, although we expect this may be an early development.

The virtues of such an achievement, that is, the storage of unfertilized eggs, would be manifold in that storage of eggs, instead of embryos, overcomes numerous ethical, social and legal concerns.

Thanks to the commercial availability of pure follicle stimulating hormone, we can collect 5 to 10 good eggs from most patients now. The medical therapeutics would be made more simple by this approach of storing unfertilized eggs.

The second example is male infertility. It is sometimes associated with too few sperms and sometimes with sperms that do not fertilize the wife's eggs. There are perhaps a million such cases in the United States alone. Accordingly, we seek to develop means for these men to achieve fertilization in vitro either by causing fusion of the egg and sperm artificially—this occurs naturally, of course, in fertile couples—or by microsurgical placement of the sperm into the ooplasm of the egg.

The third short term example that I offer goes as follows: Presently, we have precious little qualitative knowledge of the preimplantation conceptus other than it being judged subjectively under the microscope that its development is progressive and, therefore, regarded as probably normal.

We ask, though, which embryos truly have viable potential? As Dr. Jones has indicated, even in the normal couple only one embryo in four must surely be normal. That is, when placed in the uterus can this one, this embryo, or that one, initiate and sustain pregnancy for the birth of a healthy child?

We need reliable, objective tests that are predictive of pregnancy and normalcy relative to each embryo. This would lessen the risk of multiple pregnancy associated with transfer of several concepti to the uterus.

Now let's turn our attention to three examples of long-term research opportunities.

Item 4. Given the development of essential technology, certain birth defects of genetic origin may be diagnosed in the preimplantation conceptus. Although very little work has been actually done in this area, the potential for enhancement of preventive medicine is substantial. Ultimately, diagnosis must be linked to chromosomal repair if genetic abnormalities are to be treated. That is, some flawed genes may be reparable or replaceable in order to restore the potential for normal healthy development of the embryo, fetus, child. Unless there are unforeseen breakthroughs, we are many years from realizing these sophisticated technical objectives, those required to approach these complex problems in the human embryo.

Meantime, animal models will be applied extensively until the feasibility and the consequences are well demonstrated and better understood. However, we must begin now to commit ourselves to acquiring this knowledge and capability in order to assess the real potential and capability of disease prevention through gene therapy.

Item 5. We are all aware of the unfortunate shortage of suitable human organs and tissues for transplantation. Although this problem is encountered in all age groups, it is most acute in young children, for example, those suffering biliary atresia and requiring the liver transplant.

Animal studies point to the potential of nucleus substitution to produce immunologically identical organs for transplantation to replace diseased organs. It may be possible to provide new healthy

organs whose growth and differentiation is supported by embryonic cells. Again, this technology needs time and support to learn what is feasible and how it can be acceptably applied in medical care.

The last example, item 6, is one raised to us recently by cancer biologists. They have made us aware recently that some oncogenes may have formerly performed natural and normal functions in the embryonic genes during intrauterine development, long since repressed during the procession of growth and differentiation.

However, these repressed embryonic genes may turn on, begin to function again later in life and stimulate the cancerogenic behavior in our cells. Although the relationship proposed is obscure, we have the opportunity to learn the unique cell messengers operative in the human embryo and, thereby, some factors that may turn healthy cells toward cancer in adults.

Now I'll turn my attention to the last major issue I address, which is funding research in in vitro fertilization and embryo transfer.

Both we scientists and you Members of Congress are aware that Federal research moneys have been withheld from research on human in vitro fertilization and embryo transfer. This situation stems from a former DHEW Secretary's ruling in 1975, forbidding expenditures that would support this area of research. I ask you to consider whether this is any longer appropriate.

Louise Brown, the first in vitro baby, is now 6 years of age and has been joined by approximately 700 other healthy children worldwide, more than 100 of them in the United States.

The absence of IVF/embryo transfer research support from the Department of Health and Human Services is damaging, we think, on two levels: First, the costs of the procedure are met by the private sector alone, thereby restricting the therapy to those who can afford it. Because the actual costs are about \$5,000 per case, many infertile couples are shut out. There is the issue of fairness to all who might seek this help. There is a real incentive to keep the costs down so that we can accommodate the affordability to the greatest number of patients. Accordingly, precious little money is left over to support research itself.

The consequences of the absence of Federal research dollars are to have slowed our scientific progress in infertility treatment and delayed realization of extended technologies, such as learning how we might use this new information to prevent birth defects.

The second major hazard of not supporting the research is the long-standing DHEW ruling of blocking NIH from playing its normal role in the scientific process, both intramurally and extramurally. These natural roles are at least three. First, the peer review process by which the research itself is examined with fairness to the quality of the ideas and the reasonableness of their undertaking; the debate of relevant scientific, ethical and legal issues could have occurred in the context of an ongoing process where NIH grants were reviewed and; foremostly, provision of funding for research excellence in human in vitro fertilization and embryonic development.

As you will notice by the page marked appendix B, I left NIH, in fact, 1 month ago, after being there for 15 years in fertility research and, of course, relates in part to this problem. No mentor of

young physicians and scientists beginning an academic career in reproductive medicine can deny any longer the central importance of IVF/embryo transfer research in gynecologic and obstetrical care.

The nascent technologies that derive from IVF/embryo transfer research are essential brain food for our brightest, most innovative young academicians; these are the men and women who will be practicing medicine and science, their skills lasting through the year 2030. We cannot afford to stunt their development by avoiding scientific virtues that are a part of the IVF/embryo transfer process.

Having been a steward of the taxpayers money and lived directly under these DHHS limitations in Bethesda, it is my clear opinion that the American people are not adequately treated by a policy that hinders their receipt of optimal reproductive and developmental health.

There is the need to recognize that infertility is a disease, that it denies to millions of our citizens the dignity of one of life's most fulfilling experiences: the adamant desire to bear a child.

In the present tense, we have the responsibility to provide the optimum our technology can offer these couples. In the future tense, we have an equal obligation to the generations unborn, to our children's children, to secure an even greater capability to assist them in having the healthy children they surely too will want.

We can have it both ways: sensitivity to these issues that we have discussed this morning—ethical, legal, and moral—and at the same time, the scientific advances.

The scientific process can be boosted by Federal research dollars without ignoring the ethical, social, and legal issues that concern us all.

In closing, I ask: What is more fundamental to being human than understanding the biological origins of human beings? Every one of us must have gone through the process: fertilization, embryogenesis, birth, growth, and development.

It is through greater scientific understanding of this process of renewal of human generations that we can gain the medical knowledge essential to ensure the healthy bodies and minds of future Americans. In vitro fertilization and embryo transfer research can uniquely accelerate this understanding.

I thank you, Representative Gore, and the other members of the committee, for this opportunity to address these very important issues. Thank you.

[The prepared statement of Mr. Hodgen follows:]

STATEMENT OF GARY D. HODGEN, Ph.D.

Mr. Chairman and members of the Subcommittee on Investigations and Oversight, it is a privilege to have this opportunity to address the scientific, social, ethical and legal issues emerging from new reproductive technologies. As Rep. Gore requested, my remarks will focus primarily on the scientific aspects.

The Need for Infertility Treatment

As you see in my summary (marked appendix A) of data presented at the May 1984 3rd World Congress on IVF/ET (in vitro fertilization/embryo transfer), this treatment for infertility is now a proven therapeutic success. Indeed, since I presented this data to a committee of the National Academy of Sciences, the number of children born as a result of IVF/ET therapy now surely exceeds 700, with more than 300 ongoing pregnancies. Although an exact count is not available, approximately 200 in vitro fertilization programs have been initiated worldwide; perhaps 50 of these IVF/ET programs operate in medical centers and clinics within the United States. Among established programs, where this treatment is successful in 25-35% of the treatment cycles, patient demand for this help is incessant; waiting lines remain long, despite substantial increases in the number of patients being treated with IVF/ET therapy. More importantly, the nature of the reproductive health problems being confronted through this technology is becoming increasingly complex. That is, IVF/ET is no longer a naive experimental or single-minded approach to alleviating female infertility due to irreparably damaged fallopian tubes. The number of caveat procedures, both those already developed and others anticipated, demonstrates our collective

capacity to apply this new knowledge for resolution of an ever broadening spectrum of causes of reproductive failure. For example, new techniques are providing treatment opportunities in vitro for infertile men who have too few or qualitatively diminished sperms. There is an increasing demand for donor eggs or embryos for couples unable to provide their own (eggs or embryos) because of ovarian failure or obvious risks of heritable disease. For them, this new opportunity brings the special attractiveness of experiencing the life-giving act of pregnancy and delivery as a part of the parenting process. Finally, it is important not to forget the need to improve upon present levels of effectiveness (pregnancy rate) and safety (avoidance of multiple pregnancy) for IVF/ET therapy. As you have perceived from the media and other sources, these new reproductive technologies are dynamic, undergoing refinement and re-application as extensions of previously successful treatments. What propels this process? Foremost, it is patient demand, expressed either directly or by physician referral for treatment.

The Scientific Process

Typically, IVF/ET therapy necessitates the coordinate scientific, medical and technical expertises uniquely available in a specialized team. Often these teams are comprised of 15-25 persons having highly specialized knowledges and instrumentations. Moreover, rarely is the scientific process remote from physician-scientist education and patient care. Accordingly, medical centers that have directed a major allocation of personnel, budgetary and spatial resources toward resolution of these problems in reproductive health

have provided the most scientific impetus for IVF/ET research. However, relevant and timely data are contributed by certain private IVF/ET clinics, by research programs unassociated with patient care and by corporate research through provision of improved medications, media and specialized devices designed especially for IVF/ET therapy. Often, the initial feasibility of new approaches in human IVF/ET procedures are first demonstrated in laboratory animals and/or the agricultural animal industry. These inter-relationships are spontaneous and naturally operative irrespective of more provincial primary goals.

Principal Research Objectives

Short-term

1. The freezing, storage and thawing of human embryos for subsequent transfer to infertile women is already a practical reality. However, a safe and reliable method of freezing and thawing human eggs has not been reported, although we expect this may be an early development. The virtues of such an achievement would be manifold in that storage of eggs, instead of embryos, overcomes numerous ethical, social and legal concerns. Thanks to the commercial availability of pure follicle stimulating hormone, we can collect 5-10 good eggs from most patients now. The medical therapeutics would be more simple by this approach combined with egg storage.

2. Male infertility is sometimes associated with too few sperms (oligospermia) or sperms that do not fertilize the wife's eggs. There are perhaps a million such cases in the U.S.A. alone. Accordingly, we seek to develop means for these men to achieve fertilization in vitro either by causing fusion of the egg and sperm (a spontaneous process in normal fertile couples) or by microsurgical placement of a sperm

in the ooplasm (egg).

3. Presently, we have precious little qualitative knowledge of the preimplantation conceptus other than that judged subjectively from its microscopic appearance. Which embryos have true viable potential? That is, when placed in the uterus, can this one or that one initiate and sustain pregnancy for the birth of a healthy child? We need reliable objective tests that are predictive of pregnancy and normalcy relative to each embryo. This would lessen the risk of multiple pregnancy associated with transfer of several concepti to the uterus.

Long-term

4. Given the development of essential technology, certain birth defects of genetic origin may be diagnosed in the preimplantation conceptus. Although very little work has been done in this area, the potential for enhancement of preventive medicine is substantial. Ultimately, diagnosis must be linked to chromosomal repair if genetic abnormalities are to be treated. That is, some flawed genes may be reparable or replaceable in order to restore the potential for normal healthy development of the embryo, fetus and child. Unless there are unforeseen breakthroughs, we are many years away from having the sophisticated technical knowledge required to approach these complex problems in human embryos. Meantime, animal models will be applied extensively until feasibility and consequences are well demonstrated and better understood. However, we must begin now to commit ourselves to acquiring this knowledge and capability in order to assess the real potential and acceptability of disease prevention through gene therapy.

5. We are all aware of the unfortunate shortage of suitable human organs and tissues for transplantation. Although this problem is encountered by all age groups, it is most acute in young children such as those needing liver transplantation because of biliary atresia or other causes of liver failure. Animal studies point to the potential of nucleus substitution to produce immunologically identical organs for transplantation to replace diseased ones, as well as evidence that fetal tissues do not elicit strong rejection reactions from recipients. It may be possible to provide new healthy organs whose growth and differentiation is supported by embryonic cells. Again, this technology needs time and support to learn what is feasible and how it can be acceptably applied in medical care.

6. Cancer biologists have made us aware recently that some oncogenes may have formerly performed as normal embryonic genes during intrauterine development, long since repressed during the procession of growth and differentiation. However, these repressed embryonic genes may "turn-on" later in life and stimulate cancerogenic behavior of our cells. Although the relationship proposed remains somewhat obscure, we have the opportunity to learn of the unique cell messengers operative in human embryos and, thereby, some factors that turn healthy cells toward cancer in adults.

Funding Research in IVF/ET

Both we scientists and you members of Congress are aware that federal research monies have been withheld from research on human in vitro fertilization and embryo transfer. This situation

stems from a former DHEW Secretary's ruling in 1975, forbidding expenditures that would support human IVF/ET research. I ask you to consider that this is no longer an appropriate DHHS position. Louise Brown, the first in vitro baby, is now six years of age and has been joined by about 700 other healthy children worldwide, more than 100 of them in the United States.

The absence of IVF/ET research support from DHHS is damaging on two levels: 1) Presently, the costs of the procedure are met by the private sector alone, thereby restricting this therapy to those who can afford it. Because actual costs are about \$5000 per case, many infertile couples are shut-out. There is the issue of fairness to all who might seek this help. There is a real incentive to keep costs down to accommodate affordability to the greatest number. Accordingly, precious little money is left-over for IVF/ET research. The consequences of the absence of federal research dollars are to have slowed our scientific progress in infertility treatment and delayed realization of extended technologies, such as prevention of birth defects. 2) The long-standing DHEW ruling has blocked NIH, both intramurally and extramurally, from its natural roles: a) in peer review of IVF/ET research; b) debate of relevant scientific, ethical and legal issues; and c) foremostly, provision of funding for research excellence in human fertilization and embryonic development.

As you will notice by the page marked appendix B, I left NIH one month ago after 15 years of fertility research within NICHD. Why? No mentor of young physicians and scientists beginning

academic careers in reproductive medicine can deny the central importance of IVF/ET research in gynecologic and obstetrical care today. The nascent technologies that derive from IVF/ET research are essential "brain food" for our brightest, most innovative young academicians; these are the men and women who will be practicing their medical and investigative skills through the year 2030. We cannot afford to stunt their development by avoiding the scientific virtues of IVF/ET. Having been a steward (civil servant) of the taxpayers money and lived directly under these DHHS limitations in Bethesda, it is my clear opinion that the American people are not adequately treated by a policy that hinders their receipt of optimal reproductive and developmental health.

There is the need to recognize that infertility is a disease that denies to millions of our citizens the dignity of one of life's most fulfilling experiences--the adamant desire to bear children. In the present tense, we have the responsibility to provide the optimum our technology can offer these couples. In the future tense, we have an equal obligation to the generations unborn, to our children's children, to secure an ever greater capability to assist them in having the healthy children they too will want.

We can have it both ways! The scientific process of IVF/ET can be boosted by federal research dollars without ignoring the ethical, social and legal issues that concern us all. In closing, I ask: What is more fundamental to being human than understanding the biological origins of human beings? Every one of us must have gone

through this process: fertilization, embryogenesis, birth, growth and development. It is through greater scientific understanding of this process of renewal of human generations that we can gain the medical knowledge essential to insure the healthy bodies and minds of future Americans. In vitro fertilization and embryo transfer research can uniquely accelerate this understanding.

I thank Rep. Gore and each of the members of the Subcommittee for this opportunity to address these important issues.

August 8, 1980

Date

Gary D. Hodgen

Gary D. Hodgen, Ph.D.

APPENDIX A

SUMMARY OF CURRENT STATUS OF IN VITRO FERTILIZATION
AND EMBRYO TRANSFER THERAPY¹

Gary D. Hodgen, Ph.D.²
Chief, Pregnancy Research Branch
NICHD, NIH, Bethesda, MD 20205

[Data from 3rd World Congress on IVF/ET in Helsinki, May 13-17, 1984]

1.	Number of programs in operation for more than one year (more than 200 starting in '84-'85)	= ~ 70										
2.	" " providing current data	= 58										
3.	" " treatment cycles	= 9,641										
4.	" " oocytes collected at aspiration	= 24,037										
5.	" " embryos transferred to uterus	= 7,722										
6.	" " deliveries	= 516										
7.	" " children born (50.1% ♂ ; 49.9% ♀)	= 590										
8.	" " twin pregnancies	= 56										
9.	" " triplet pregnancies	= 7										
10.	" " quadruplet pregnancies	= 1										
11.	" " birth defects reported	= 4										
	a) Heart valve anomalies = 2											
	b) Extra digit = 1											
	c) Trisomy 21 = 1											
12.	Pregnancy rate (pregnancies/transfer cycle) (overall)	= ~ 25%										
	a) 1981-1982 = ~ 12%											
	b) Programs operating 4 or more years = ~ 35%											
	c) Women over 40 years of age = < 5%											
	d) Effect of number of embryos transferred											
	<table><tr><th>Embryos Transferred</th><th>Pregnancy Rate</th></tr><tr><td>1</td><td>10.3%</td></tr><tr><td>2</td><td>15.5%</td></tr><tr><td>3</td><td>20.2%</td></tr><tr><td>4 or more</td><td>24.6%</td></tr></table>	Embryos Transferred	Pregnancy Rate	1	10.3%	2	15.5%	3	20.2%	4 or more	24.6%	
Embryos Transferred	Pregnancy Rate											
1	10.3%											
2	15.5%											
3	20.2%											
4 or more	24.6%											

¹Presented to: NATIONAL ACADEMY OF SCIENCES, Genetic Manipulation of the Human Germline Planning Group, June 6, 1984.

²New address (7-1-84): Scientific Director, The Jones Institute for Reproductive Medicine, Department of Obstetrics and Gynecology, Lewis Hall, Room 2049, Eastern Virginia Medical School, Norfolk, VA 23501

Published in: SCIENCE, March 2, 1984

Scientist Quits NIH Over Fetal Rules

Gary Hodgen, an ambitious specialist in fertility and pregnancy research, soon will be leaving the National Institutes of Health (NIH) to become scientific director of the Institute for Reproductive Medicine at the Eastern Virginia Medical School in Norfolk. His departure reflects his growing frustration with how rules restricting federal research on human fetuses are being interpreted, and the detrimental effect the rules may have on a wide variety of biomedical research. His leaving may also spell the end for much of NIH's intramural research on infertility and for several influential training programs.

Chief of the pregnancy research branch at NIH since 1978, Hodgen has worked on the Bethesda campus since he completed graduate work in 1969. He has nothing but high praise for the "nurturing atmosphere" of NIH, which he says has provided him with "truly exceptional opportunities." Nevertheless, current federal restrictions limiting government-funded research in reproductive medicine and NIH's narrow interpretation of them no longer make the Bethesda campus a conducive setting for his research.

Ten-year-old regulations governing federal support of in vitro fertilization, which are interpreted to encompass virtually all research on human embryos, specify that individual research proposals must be reviewed by a feder-

ally appointed ethics advisory board. But the appropriate board was disbanded in 1980, and thus no research in this area can be done until it is reinstated. (One or several such boards would deal with other categories of research—now also prohibited because review is impossible—involving children or prisoners.) Several months ago NIH sent a request for the board's reestablishment to the Department of Health and Human Services (HHS), and a set of options has been forwarded to HHS secretary Margaret Heckler. She has not yet ruled on the matter.



Gary Hodgen

ally appointed ethics advisory board. But the appropriate board was disbanded in 1980, and thus no research in this area can be done until it is reinstated. (One or several such boards would deal with other categories of research—now also prohibited because review is impossible—involving children or prisoners.) Several months ago NIH sent a request for the board's reestablishment to the Department of Health and Human Services (HHS), and a set of options has been forwarded to HHS secretary Margaret Heckler. She has not yet ruled on the matter.

The absence of an ethics advisory board is "frustrating some of our scientists who can't work on very important problems," says Mortimer Lipsett, director of the Institute of Child Health and Human Development where Hodgen has worked. Oddly enough, although antiabortion groups have been the strongest critics of in vitro fertilization, many of the scientific problems Lipsett alludes to can be construed as "pro-life" because they are aimed at improving an embryo's chances for survival. For example, one of Hodgen's research goals is to develop methods for diagnosing and correcting abnormalities in fetuses. Opponents have often discouraged research on embryos, arguing discovery of defects will lead to more abortions. Hodgen argues otherwise, saying: "We propose a middle

ground . . . If we had the knowledge and ability [to correct defects in fetuses], the mother might not want to elect abortion."

Despite this seeming congruence between Hodgen and critics of this research, the whole issue of in vitro fertilization and medical investigations on human embryos is being treated with extreme sensitivity by NIH. On several occasions, for example, permission for Hodgen to participate in scientific meetings dealing with these issues was withdrawn by NIH officials to avoid giving any impression that certain kinds of research were being advocated.

The most celebrated instance came in September 1982 when Hodgen was told not to attend a workshop being held—ironically now that he soon will be moving there—at Eastern Virginia Medical School. Hodgen says there were altogether three instances during his 14 years at NIH where administrators "infringed on his academic freedom" in this way. He was asked not to attend the 1982 conference to avoid "the appearance of conflict" with official policies, even though his work has adhered to those policies. Similarly, his scientific papers sometimes have been subjected to extra scrutiny and last-minute editing for reasons other than scientific clarity. "I have not felt this was censorship," Hodgen says, "but I think this is irregular . . . and has to do with perceived sensitivity" to the implications of his work.

By confining his studies to monkeys and other lower-order mammals, Hodgen has avoided any major confrontation with federal officials over the propriety of his research. But another frustration for him has been the impossibility at NIH of "translating" any of his results directly into clinical practice. Although NIH has a small program devoted to several aspects of human infertility, many issues simply cannot be addressed. For example, Lipsett points to the important medical problem in the United States of low birth weight, which in a broad sense contributes to the infertility picture because it affects infant mortality. Sheep studies indicate that amino acid supplements introduced directly into the amniotic fluid can allay this problem, but the technique cannot be applied to humans before proper studies are undertaken. However, appropriate studies cannot be done because there is no board to review proposals.

Hodgen's long-range interests include plans to study the feasibility of gene therapy in embryos, with the ultimate aim of preventing birth defects. His current proposals call for taking up this study in monkeys, but his ambition is to preside over the "confluence of reproductive and molecular biology in human medicine." This is a "big idea," he says, "We are far from realizing it. [But] I want to participate."

By not reinstating an ethics review board, the government has discouraged some scientists from seeking federal support for reproductive research and now has prompted Hodgen to leave NIH saying his "patience is worn out" waiting for such a change. It may prove a serious mistake to drive scientists such as Hodgen out of federal institutions, where research is done openly and its consequences may be debated while the work is progressing. When research must be done in the private sector, debate usually is postponed until results are announced.—JEFFREY L. FOX

BIOGRAPHICAL SKETCH

Gary D. Hodgen, Ph.D.

Education

1969 Ph.D. Reproductive Physiology, Ohio State University

1969-1973 Postdoctoral Fellowship in Reproductive Medicine, National Institutes of Health, Bethesda

Professional Positions

1973-1978 Head, Section on Endocrinology, Reproduction Research Branch, NICHD, NIH, Bethesda

1978-1984 Chief, Pregnancy Research Branch, NICHD, NIH, Bethesda

1984-Present Scientific Director, The Jones Institute for Reproductive Medicine, Dept. OB/GYN, Eastern Virginia Medical School, Norfolk

Selected Honors and Awards

1981 Recipient, SSR Research Award spanning 1975-1980, Society for the Study of Reproduction.

1982 Presenter, The Ayerst Lecture, American Fertility Society, Las Vegas, Nevada. "The Dominant Ovarian Follicle".

1982 Presenter, The Gregory Pincus Memorial Lecture, The Laurentian Hormone Conference, Mont Tremblant, Canada. "The Ovarian Triad in the Primate Menstrual Cycle".

1982 Presenter, The Ortho Lecture. Canadian Committee for Fertility Research, Montreal, Quebec. "Ovarian Function in the Menstrual Cycle: Implications and Speculations".

1983 Recipient, The President's Scientific Achievement Award, The Society for Gynecologic Investigation.

1983 Recipient, The Public Health Service Superior Service Award, DHHS

1984 Recipient, Pioneer on In Vitro Fertilization Award, The International Committee of In Vitro Fertilization and Andrology

1984 Presenter, The New York Obstetrical Society, "New Developments in Ovarian Stimulation, Fertilization and Embryo Transfer", The Yale Club, New York City.

Selected Scientific Consultant Services

- 1980-Present Advisory Committee on In Vitro Fertilization, Reproductive Sciences Branch, Center for Population Research, National Institute of Child Health and Human Development, National Institutes of Health
- 1980 Chairman, Scientific Session, In Vitro Fertilization Workshop: Gamete Collection for In Vitro Fertilization; Center for Population Research, Reproductive Sciences Branch, National Institute of Child Health and Human Development, National Institutes of Health
- 1980 Member, Evaluation Review Panel on Human Infertility, Division of Research Grants, NIH
- 1982 Consultant, The Andrew W. Mellon Foundation, N.Y.
- 1982 Consultant, The Population Council, Rockefeller University, NY
- 1983 Moderator, Reproductive Investigations Session on Gametes, Fertilization, and Preimplantation Embryos, The American Fertility Society, 39th Annual Meeting
- 1983 Scientific Advisor for Reproductive Biology, "Ethical and Public Policy Aspects of Prenatal Technologies" by Dr. Leroy Walters, The Joseph and Rose Kennedy Institute of Ethics, The Georgetown University, Washington, D.C.
- 1983 Moderator, Symposium, "Dynamics of Ovarian Follicular Maturation", The Society for Gynecologic Investigation, Washington, D.C.
- 1983 Consultant, The Ford Foundation, International Division for Population
- 1984 Scientific Committee, 4th World Conference on In Vitro Fertilization, Melbourne, Australia
- 1984 Moderator, Symposium: "Research Opportunities Derived from In Vitro Fertilization and Embryo Transfer Therapy". Society for Gynecologic Investigation, San Francisco, CA.
- 1984 Member, National Academy of Science's Committee on Manipulation of the Human Germ Line, Washington, D.C.

Scientific Publications

223 Original Articles, Chapters and Books

Mr. GORE. Thank you very much. I appreciate your testimony, both of you.

I said a moment ago, Dr. Jones, that in my opinion, most Americans realize very clearly what a blessing it is for these mothers and fathers who have been unable to have children by normal and traditional means to have children through the technique that you have pioneered in this country.

Nevertheless, questions do remain, and when confronted with those questions initially, in your statement, you cited the AFS Guidelines—the American Fertilization Society Guidelines. You were chairman of the panel that developed these guidelines; is that correct?

Dr. JONES. That's correct.

Mr. GORE. In your view, do they suffice to deal with the bioethical questions that you confront in your practice?

Dr. JONES. They seem to, yes.

Mr. GORE. Who oversees—who is responsible for overseeing these guidelines?

Dr. JONES. There is no overseeing body—

Mr. GORE. There's no oversight?

Dr. JONES [continuing]. Except for the general public, who, naturally, would request and see that they are found.

Mr. GORE. Are there any penalties if these guidelines are violated?

Dr. JONES. There is the penalty of the criticism of one's colleagues.

Mr. GORE. OK. So the only—the only enforcement mechanism relies upon the physician's sensitivity to what the public and his colleagues might think about what he's doing.

Dr. JONES. That's a very powerful force.

Mr. GORE. I don't doubt that it is. Some would say it's not powerful enough in light of medical history.

Do you think it is powerful enough?

Dr. JONES. I think it's very powerful.

Mr. GORE. Do you think it's powerful enough?

Dr. JONES. It seems to me to have worked very well indeed. I have difficulty citing an example where it has not been operational in this regard.

Mr. GORE. Often it's the case that in these new areas there is a heightened sensitivity during the early stages; and then after the practice is continued for a generation, say, there's kind of a lapse in the extreme sensitivity to what the public or one's colleagues might think as new frontiers are encountered and new decisions have to be made. You understand what I'm getting at.

It may be that while you are so very sensitive to these bioethical questions now because you are a pioneer. Those who follow you may practice in a very different bioethical environment and the approbation of colleagues and the general public may not hold the same terrors—or discipline, if you will—for them as for you.

Is that a legitimate concern?

Dr. JONES. Well, it's certainly a concern, as I think back about the innovation of new things in medicine. I'm not sure I can easily cite an example of where the factors that you're mentioning have come into play—perhaps there are some. I would have to think

about that a little bit. But I can't think of an example of where that would apply.

I understand what you say, but as I search for an example, I have a little difficulty coming up with one.

Mr. GORE. All right. Well, let's look at the guidelines themselves that you say suffice for—appear to suffice, or have sufficed—in your experience. We'll give you a copy of them. Do you have them?

Dr. JONES. I don't have a copy of them.

Mr. GORE. Let me ask the staff to give you a copy just to refresh your memory on these.

You say that the concepti or the property of the donors—now, concepti—a conceptus is——

Dr. JONES. Fertilized egg.

Mr. GORE [continuing]. A fertilized egg. At what point—let's get our terms straight here, OK?

Dr. JONES. OK.

Mr. GORE. What's the first thing you have? A fertilized egg is a conceptus.

Dr. JONES. Yes, I think so.

Mr. GORE. Is there a stage before that? What——

Dr. JONES. Well, you have the egg and the sperm.

Mr. GORE. And that's it. OK. Now, what's a gamete?

Dr. JONES. A gamete is a synonym for an egg or a sperm.

Mr. GORE. All right.

Dr. JONES. Another word—you can use it either—for either one.

Mr. GORE. All right, OK.

Now, conceptus is the early stage. Then you get to, what, the cytotblast next?

Dr. JONES. Actually, the word conceptus can apply to anything during any stage of development.

Mr. GORE. All right, fine. It begins—all right.

Another term is obviously embryo. At what stage is an embryo created?

Dr. JONES. Well, I think among biologists you'll find a good bit of difference of opinion about that. I think it's easier to say when it is not an embryo. And certainly in the undifferentiated stage, as Dr. Hodgen mentioned, where the cells of the early conceptus can individually produce an individual, I don't think we have an embryo.

Mr. GORE. At what stage—at what time do you cross that threshold?

Dr. JONES. Well, as I said, I think there's a lot of difference of opinion among embryologists about that particular point. I do not consider myself an expert embryologist in this regard. It has not been possible, my understanding, to have individual development at the 8-cell stage, but I'm not sure that that necessarily means we are then dealing with an embryo. But we have among embryologists some opinion that at about 14 days we have enough differentiation to think of that in terms of an embryo. This is different from an individual.

But we are now, I think, talking technical languages so we can communicate.

Mr. GORE. I understand. Now, that—so there is an emerging consensus that, within the medical community, that at 14 days, or

about 14 days, an embryo is present as defined by the—the appearance of—

Dr. JONES. I would tend to put it the other way around, namely, that prior to 14 days there is not an embryo.

Mr. GORE. There is a preembryo, or a—

Dr. JONES. Well, there's something that's going to develop into an embryo later on.

Mr. GORE. OK.

Dr. JONES. Some part of that—

Mr. GORE. Now, at what point is there a cytotblast?

Dr. JONES. I think we need to ask an embryologist that a little more—

Mr. GORE. All right, we'll have one on later on, so we'll defer those then, OK.

But I wanted—my first question to you provoked that because you say the concepti are the property of the donors. Would you also say that the embryos are the property of the donors?

Dr. JONES. Well, I think the word property here is used in the sense of the parents having a certain say in the ultimate disposition of them.

Mr. GORE. They have the—the exclusive say, by your guidelines.

Dr. JONES. They have the exclusive say, that's correct.

Mr. GORE. So the embryo can be disposed of, or used for scientific research, or implanted at the sole discretion of the donors, under your guidelines?

Dr. JONES. That would be customary in dealing with patients who wish to be operated on, or have the opportunity to be operated on—we usually give them the opportunity to say what they would like done. And this is a continuation of that standard medical concept.

Mr. GORE. Now, that doesn't seem to leave much—much room for consideration by those involved in the process for any rights, hypothetical or otherwise, assigned to the embryo. The embryo is—is totally at the—at the mercy of the donors. And you have no—under these guidelines—you have no obligation to consider any rights that might independently adhere to the embryo. Correct?

Dr. JONES. It was the judgment of the committee that that was a very workable arrangement.

Mr. GORE. I'm sure it's workable. I'm sure it's workable. The—and, and—but workability and—and bioethics are not always exactly congruent. Now, your fourth—your fourth principle here says it is—it is considered ethically acceptable to scientifically examine any conceptus donated for this purpose, provided such examination is carried out prior to the time development has reached the stage when implantation would normally occur.

Now, when is the stage when implantation would normally occur?

Dr. JONES. Well, it says here that this is considered to be 14 days after insemination.

Mr. GORE. Fourteen days. OK.

Now, Dr. Hodgen, you've thought a lot about this question, I know, because this—these problems form the basis of the dispute which eventually led you to leave the Federal Government and go to work for Dr. Jones.

If the donors give you the embryo—is it OK to call it an embryo?

Mr. HODGEN. I think in the parlance, yes, if we understand that there's, there's this lack of total clarity——

Mr. GORE. All right.

Mr. HODGEN [continuing]. I can accept the use of the word, yes.

Mr. GORE. All right, all right.

It makes the question a little more pointed, it may not be exactly on target.

Mr. HODGEN. That's fine.

Mr. GORE. If the donors give you the embryo for—to use for experiments? Can I use that word?

Mr. HODGEN. Yes.

Mr. GORE. At what point is it—do you ever consider, or should you ever consider, the—the rights of that embryo in undergoing the experimentation? You understand the question I'm getting at—perhaps your first answer will help me to clarify a followup question.

Mr. HODGEN. Yes. In an absolute sense, we do not address rights of an embryo because we go through the following cascade: In a proprietary way, the embryo and decisions about its ultimate destiny, as they can be influenced by persons, that's controlled as a decision by the man and woman who are responsible for the egg and sperm that lead to the embryo.

The second is, they make a decision if they do not wish to use it to have potential for pregnancy themselves——

Mr. GORE. Uh-huh.

Mr. HODGEN [continuing]. They may choose altruistically to donate this to a couple who is very desirous of having this help.

Mr. GORE. Uh-huh.

Mr. HODGEN. A third desire they could express is to make the decision that the embryo will be used for scientific study, to gain the knowledge that will lead to improvements of the procedure for other people, or to entirely new endeavors—some of which I outlined in my presentation.

Under that scenario, there is no direct address to rights of an embryo in the sense that it has personhood or those kinds of issues.

Mr. GORE. So you don't consider it?

Mr. HODGEN. I don't think we consider it in an overt fashion, because, as I've described it would be a matter of saying, if we consider them, how do we do that? That would be the question I would ask back. And in that sense, we do not address the embryo as a person, as an individual with rights and privileges as inherent to personhood.

I think a part of the whole ethical, moral, legal dilemma that we're in is because this debate has not gone as rapidly as it should. This meeting is more than timely, it's penultimate timely. Perhaps we should have been busier as a society, pulling our ideas along with the technology even before now, but very glad to be here this morning.

Mr. GORE. Well——

Mr. HODGEN. But in your question, I couldn't say to you that we do address the rights of an embryo because there's no manifestation of that in the decisionmaking process.

Mr. GORE. All right, now let's look at the decisionmaking process. You say, essentially, that—that you are going to rely on the donors to make that bioethical judgment for you.

Mr. HODGEN. Yes; and one other thing. This set of guidelines, which is—which is a set of limits upon given the extent of biological understanding as we know it—that is, of course, a real limit, but always changing—as we understand it, differentiation has not yet begun up through day 14 after fertilization. Given that limitation as a second adherent, then I could agree to what you've just posed.

Mr. GORE. Now, why is that important to you?

Mr. HODGEN. I think it's important because as we understand embryology now, we think beyond 14 days, the process we call differentiation, begins. That is the the genetic potential in—inherent to this embryo, begins to decide which cells will make this an individual by characteristics.

Mr. GORE. But that's—

Mr. HODGEN. The cells that will make bone or intestine, or brain, or whatever.

Mr. GORE. Yes.

Mr. HODGEN. Now, up to that point in time, differentiation, although it has begun in more subtle ways, it has not yet manifested itself. And one must—one must address the issue of how far one would go in time in studying this developmental process for the sake of learning.

Mr. GORE. Well, it's kind of an arbitrary—

Mr. HODGEN. Indeed it is—arbitrary for several reasons: One, we could choose—we could give other reasons to choose a different time.

Mr. GORE. Yeah.

Mr. HODGEN. But also arbitrary because our understanding is so incomplete.

Mr. GORE. Well, now, after—let's accept your arbitrary limit for a moment, and let's say that after 14 days differentiation has begun. Why—on the 15th day, do you believe it's ethically wrong to conduct an experiment?

Mr. HODGEN. I would—I would say that choosing 14 versus 15—

Mr. GORE. Yeah.

Mr. HODGEN [continuing]. Is—is done because, as we are in this very meeting, we're searching for some degree of consensus.

Mr. GORE. Yeah, yeah.

Mr. HODGEN. Two committees, large committees, addressed this same question, and they also came to 14 days.

Mr. GORE. Yeah.

Mr. HODGEN. The first of those was the NIH Advisory Board, and that report, of course, appearing in 1979, made the same judgment: day 14 would be the limit of experimental uses of human embryos. And then the Warnock report, to which you commented early this morning, made the same decision. So we're looking here for—

Mr. GORE. Well, they went the distance, they went further. And—and in England, they recommended that it be a criminal offense—

Mr. HODGEN. Well, that's—that's looking—

Mr. GORE [continuing]. To conduct any experiment following 14 days.

Mr. HODGEN. That would be if someone violated—what we call a guideline, they have recommended that it become law, a legal limit.

Mr. GORE. Yeah.

Mr. HODGEN. But they also chose 14 days, and——

Mr. GORE. Would you agree with that recommendation?

Mr. HODGEN. Yes; I think for now that's, that's a—that's a safe point at which to draw the line until understanding allows us to reconsider.

Mr. GORE. But that whole distinction rests upon the rather—well, I started to say rather questionable, maybe that's not a fair way to put it. But it rests upon the arguable assumption that before 14 days there isn't differentiation. And translated, what you're really saying there is, there isn't an individual entity.

Mr. HODGEN. Yes; at day 14, we have, for the first time in the human, a clearly—a set of cells that become the placenta—the support tissues, and another set of cells——

Mr. GORE. We have—we have for the first time a differentiation that our current scientific——

Mr. HODGEN. That's it.

Mr. GORE [continuing]. Instruments can detect.

Mr. HODGEN. That's it. So it's—it's a break point only because it's one we recognize and understand, at least in part.

Mr. GORE. Uh-huh.

Mr. HODGEN. All of this is obviously a continuum, so any break we make is artificial by our—by our intervention.

Mr. GORE. Now, so that we're clear, these—these experiments often damage the—the embryo.

Mr. HODGEN. They could. And some of the experiments would—would consume any life support properties of the embryo. If the embryo were—were used to examine it anatomically by fixation and placement on a slide as we do a biopsy of liver, or kidney, or any other——

Mr. GORE. Yeah.

Mr. HODGEN [continuing]. Body part—in that sense, yes.

Mr. GORE. Now, the—the persons upon whom you are relying to make the judgment that it's OK to do this, are persons who are emotionally indebted to you, are they not?

Mr. HODGEN. Yes, they are, but there's another group we haven't talked about, that participate in a very real way. Each institution that performs these procedures has what's called an institutional review board—a set of individuals who are not themselves standing in a position where they have a particular leverage upon the set of ideas being proposed. And they are there for a very important reason: to help as a form of jury, if you will allow me to use it in the broadest context, of making a judgment as to whether what's being proposed is feasible, safe, and reasonable, given their collective ability to assess the social mores and understanding.

So they, too, have participated if this is to be undertaken. If embryos are to be used for research purposes, first, there would have to be, from the beginning, the consent and willingness and the fol-

lowing through then of execution of the wishes of the man and woman that led to the fertilization.

Second, there would have to be in place this review panel at the institution to which we, as scientists, had submitted our ideas, our rationales, our justifications, for using these tissues for knowledge-gaining purposes—

Mr. GORE. We're going to—

Mr. HODGEN [continuing]. For training new physicians and scientists.

Mr. GORE. We're going to hear from representatives of one of those boards on the next panel, and look at how one hospital, one community—

Mr. HODGEN. Yes.

Mr. GORE [continuing]. Wrestle with these decisions. But that board doesn't review each decision. It reviews the generic experiment to see if on balance its value justifies the experimentation.

Mr. HODGEN. That's basically correct.

Mr. GORE. But the individual decisions are still made by the donors.

Mr. HODGEN. Yes.

Mr. GORE. Now, by turning over—if you turn over your responsibility to make those individual decisions, if you have one, if you say the responsibility belongs with the donors, you have an interest in proceeding with the—with the experiments, they are emotionally indebted to you. Is the—is that system tilted toward an approval for the experimentation?

Mr. HODGEN. I think it could be, but I believe that the question, if I could, in answering, turn it slightly—

Mr. GORE. Uh-huh.

Mr. HODGEN [continuing]. I think Dr. Jones could respond. I think it's the relationship between the physician and the infertile couple where this decision is made that is largely the controlling point. And I believe it is up to the physician involved to not misuse—

Mr. GORE. Yeah.

Mr. HODGEN [continuing]. That relationship. And that's true in all other areas of medicine, of course, and very true in this one the same way.

Mr. GORE. OK. Certainly some bioethicists would—would be less than satisfied with the American Fertility Society guidelines. But I commend the Society and also ACOG, the American College of Obstetricians and Gynecologists, for going into this field and trying to establish some guidelines where none exist. They have not been reviewed, or approved, or sanctioned by anyone other than—than the people who were in the field, and who were on this board.

Without objection, we will put these guidelines into the record at this point.

[The guidelines follow:]

Ethical statement on in vitro fertilization

American Fertility Society**

- I. In vitro fertilization for infertility not solvable by other means is considered ethical.
- II. It is understood that any couple entering into a program of in vitro fertilization will have discussed and signed a proper consent form covering the various steps in the procedure. It is understood that the gametes and concepti are the property of the donors. The donors therefore have the right to decide at their sole discretion the disposition of these items, provided such disposition is within medical and ethical guidelines as outlined herein.
- III. In the event there are concepti in excess of those required for transfer in the harvest cycle, they may be treated at the option of the couple in accordance with paragraphs IV, V, or VII.
- IV. It is considered ethically acceptable to scientifically examine any conceptus donated for this purpose, provided such examination is carried out prior to the time development has reached the stage when implantation would normally occur. For purposes of this paragraph, 14 days after insemination is considered to be the limit.
- V. Nontransferred concepti should not be allowed to develop in the laboratory more than 14 days and may be disposed of without scientific examination.
- VI. Cryopreservation of concepti for the purpose of subsequent implantation into the female partner is acceptable with certain provisions. The concepti should not be retained in the cryopreserved state for longer than the reproductive life of the female donor. However, the disposition of any unused cryopreserved concepti should be provided for prior to cryopreservation and in accordance with the guidelines of paragraphs IV, V, or VII.
- VII. After the reproductive problem has been resolved to the satisfaction of the donors, it is considered ethically acceptable to donate to another infertile couple nontransferred concepti, provided any claim to any resulting progeny is waived and provided strict anonymity between donors and recipients is assured as in any adoptive procedure.
- VIII. Donor sperm should be looked upon as any other donor insemination technique and should be considered ethical and sound for those males that even with in vitro fertilization cannot fertilize normally.
- IX. Donor oocytes should be considered ethical and sound for those females who have no oocytes or whose oocytes cannot yield adequate embryonic fertilization.

*Report of an ad hoc committee of The American Fertility Society. Howard W. Jones, Jr., M.D., Chairman; Anne Cassman, Nancy M.D., Martin M. Margolis, M.D., Richard P. Marx, M.D., and J. Allen Packer, M.D., Advisors to the Board of Directors of The American Fertility Society.

**Revised Statement on In Vitro Fertilization, Society of Obstetricians and Gynecologists, 1983.

Minimal standards for programs of in vitro fertilization

American Fertility Society

I. General Considerations

Every group initiating a program of in vitro fertilization should have all aspects of the program approved by a properly constituted Institutional Review Committee. The Institutional Review Committee or its equivalent should ensure that a record is kept of all attempts made at securing pregnancies by these techniques. The records should include all medical aspects of the treatment cycles and a record of success or failure with respect to oocyte recovery, fertilization, cleavage, conceptus transfer, biophysical monitoring of fetal growth, pregnancy outcome, and complications. These institutional records, which should be separate from the regular records of the medical institution, should be confidential. Summaries for statistical purposes, including details of any congenital abnormalities among offspring, should be available for correlation.

It is recommended that special attention be given to the emotional needs and the emotional support of these patients.

It is recommended that the director of the program have clinical experience and competence.

In view of the many research opportunities offered by programs of in vitro fertilization, it is urged that all programs be

designed to take advantage of these opportunities.

II. Personnel

Personnel with the following four types of skills are required as a minimum. A single individual may possess one or more of the required skills.

(1) An individual with the experience and training required for board certification in reproductive endocrinology. While individuals with equivalent training and experience are certainly acceptable, board certification clearly indicates that the required skills in reproductive endocrinology have been obtained.

(2) A pelvic reparative surgeon with laparoscopic experience with evidence of specialized training in follicular aspiration.

(3) An individual experienced in male reproduction (andrology) with special competence in semenology.

(4) An individual with knowledge of and practical experience in tissue culture, gamete maturation, fertilization, and early zygote cleavage in human and animal systems.

III. Special Services and Facilities

These services and facilities must be on call on a daily basis with 24-hour availability.

- (1) Ultrasonography
- (2) Hormonal assays
- (3) Facilities for follicular aspiration and conceptus transfer
- (4) Anesthesia
- (5) A laboratory for gamete fertilization and conceptus development near the operating room with two-way communication between the laboratory and operating room.

*Report of an ad hoc committee of The American Fertility Society: Howard W. Jones Jr., M.D., Chairman; Anne Colston Wentz, M.D.; Martin M. Quigley, M.D.; Richard F. Matre, M.D.; and L. Allen Paulson, M.D., approved by the Board of Directors of The American Fertility Society.

Reprint requests: The American Fertility Society, 1335 Avenue South, Suite 104, Birmingham, Alabama 35204.

Mr. GORE. Dr. Jones, are you using frozen embryos now? Are you using the cryopreservation technology now?

Dr. JONES. No, we are not.

Mr. GORE. Why not?

Dr. JONES. Well, I think it has a medical attractiveness, as I have indicated, and we simply haven't gotten around in our list of priorities to having a look at that on our—in our own program.

Mr. GORE. Does it worry you that all of the data on effects of freezing embryos has come from animal work?

Dr. JONES. Well, I think when we started in vitro fertilization, basically all our data were from the animal, and the animal data were persuasive enough to lead us to believe that it was reasonable to proceed in the human, and I think we're essentially at that point in the freezing situation.

Mr. GORE. Are there advantages to the frozen embryo technique which mitigate toward its usage?

Dr. JONES. Well, you mean as opposed to other techniques? I think there is a great advantage of being able to hold over for a second try in the event of failure without putting the patient through the procedure required to harvest eggs.

Mr. GORE. Yes.

Dr. JONES. So I think from—that's a very attractive medical point. And if somehow or other we could accomplish that, whether it's by freezing or whatever, it would greatly facilitate the practical application of in vitro fertilization.

Mr. GORE. My understanding—and correct me if I'm wrong—is that by holding over frozen embryos after a first attempt at pregnancy, the doctors can avoid exposing the woman to the risks of the laparoscopy—is that the word for it?

Dr. JONES. Yes.

Mr. GORE [continuing]. Of the surgical removal of the eggs for the second try. And, second, it is easier to—you can also avoid the possible risk associated with the drug therapy for—the drug use for supra-ovulation. Is that a part of it also?

Dr. JONES. Right. Well, the risks that you mention are real but very minimal.

Mr. GORE. Yeah.

Dr. JONES. I think the most practical point is that it would be a great deal less expensive to be able to cut out one procedure—

Mr. GORE. Yeah.

Dr. JONES [continuing]. And would be much more efficient from a clinical point of view.

Mr. GORE. Yeah. Now, you are not doing lavage either, are you?

Dr. JONES. No, we're not.

Mr. GORE. Now, lavage—correct me if I'm wrong on this term—this involves the donation of an embryo where a donor mother conceives inside her body, and the fertilized egg, or conceptus, is then flushed out by the use of a nonsurgical technique, a fluid that brings the fertilized egg out with it, and then that fertilized egg is implanted into the new mother that was unable to conceive by the normal method. One difference is that the genetic—half the genetic information is from the donor mother.

And we're going to hear about this from the person who developed it, Dr. Buster, tomorrow, along with some patients, and others.

But do you have questions about this technique, Dr. Jones?

Dr. JONES. Well, we have not thought that that had the highest priority to solve that particular problem. We have preferred to use the donor egg approach simply because it avoided even the slight risk to the donor mother. And it is only on that basis that we have preferred to use the other approach to solving that same problem.

Mr. GORE. The Warnock report recommends a prohibition against lavage, the lavage technique, and also the freezing of eggs. Basically they recommended the prohibition of lavage on the basis of its danger. Do you agree with that?

Dr. JONES. I believe the Warnock commission was divided on that. I think there was a minority report on that particular point.

Mr. GORE. But the majority recommended prohibiting it.

Dr. JONES. The majority recommended prohibiting it.

As I indicated before, we have preferred an alternate approach to that in order to avoid the slight risk to the donor. I'm not sure I would go to the extent of prohibiting it entirely. But from a personal point of view, I have indicated my position.

Mr. GORE. What about genetic manipulations of embryos prior to transplantation, or medical interference with the embryos, even those necessary for the proper development of embryos in vitro? Should those be tolerated?

Dr. JONES. Well, I think we need to define our terms here and what we're trying to accomplish.

Mr. GORE. OK.

Dr. JONES. I think, first of all, we need to mention that I believe we're now discussing something that is not in the immediate future, that we're discussing something that may happen way down the road. So that—

Mr. GORE. Some would disagree with the—with the use of the word "way."

Dr. JONES. Right. Well, I'm not sure how far I'm talking about. But at least this is not something that we can think of applying in the foreseeable future. I think one of the goals of people that deal with genetic abnormalities is to be able to overcome them. At the present time, we are—our method of handling genetic problems is confined to amniocentesis and the termination of pregnancies which are genetically abnormal.

I think it would be infinitely better if it were possible to alter the genes so that we did not have to terminate those pregnancies. So that I believe if we somehow or other could overcome the gene for Tay-Sachs disease or whatever gene we're talking about, that this would be a tremendous step forward which would be welcome by almost everyone.

Mr. GORE. Well, I have other questions but we're going to have to move on. I want to thank you both for very helpful testimony, very, very interesting. And your work is very important, and we appreciate your taking time away from it to help us try to address these difficult questions.

We have—I am going to ask now for the patience and indulgence of the witnesses on the next two panels. We have a full committee

markup and it is close to time for an early lunch, and what I think we're going to do is take a short recess. I've got a bill pending in the full committee and other members of this subcommittee are there. And we're going to take a recess for an early lunch which will last approximately 45 minutes, and we will come back here at 12:30.

The hearing will stand in recess.

AFTERNOON SESSION

Mr. GORE. The subcommittee will come back to order, please. I hope everyone got something to eat for lunch. And we're going to continue with panel 2. I'd like to call to the witness table Dr. Anne Colston Wentz, professor of obstetrics and gynecology, and director of the division of reproductive endocrinology at Vanderbilt University Medical Center in Nashville; Dr. Walter J. Harrelson, dean emeritus of the Divinity School at Vanderbilt; and Jane Buffaloe, Esq., a community member of the panel created to deal with these questions at Vanderbilt University.

Without objection, your entire statements will be included in the record and full at this point, and I want to invite you and encourage you to summarize those portions of your statement susceptible to summary without hurting the substance.

And I'd like to begin with Dr. Walter J. Harrelson. It's a real honor to have you here, Dr. Harrelson. As a former student at Vanderbilt Divinity School, I can testify to your sterling leadership of those important endeavors. And we're delighted to have the benefit of your wisdom and experience here today because you addressed many of the questions that we are addressing in this hearing in behalf of Vanderbilt.

And we want to use this as kind of a case history of how one institution and one community went about establishing a center for in vitro fertilization, and how these difficult questions were addressed. So, we'll begin with you, Dr. Harrelson. Welcome.

STATEMENT OF WALTER HARRELSON, DISTINGUISHED PROFESSOR OF OLD TESTAMENT, VANDERBILT UNIVERSITY DIVINITY SCHOOL; ANNE COLSTON WENTZ, M.D., PROFESSOR OF OBSTETRICS AND GYNECOLOGY, DIRECTOR, DIVISION OF REPRODUCTIVE ENDOCRINOLOGY, AND DIRECTOR, CENTER FOR FERTILITY AND REPRODUCTIVE RESEARCH, VANDERBILT UNIVERSITY MEDICAL CENTER; AND JANE J. BUFFALOE, ATTORNEY AT LAW, CHAIRPERSON, LEGAL/LEGISLATIVE AFFAIRS COMMITTEE OF THE ADVISORY BOARD TO THE CENTER FOR FERTILITY AND REPRODUCTIVE RESEARCH, VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, TN

Mr. HARRELSON. Thank you very much, Congressman Gore, ladies and gentlemen. I come as a witness of a different sort than those we've heard thus far today. I am a learner in this field and can only speak about a process which I was involved in and about certain things that I think I learned and we learned with regard to that process. I hope that this may be of some use, though I recognize that what I have to say is of a different order than the kinds of things we've had thus far.

Vanderbilt has the great asset of being a small university with a full complement of graduate and professional schools located on a spacious but still densely built campus. The opportunity for the sharing of ideas and problems across the lines of the disciplines in the schools is therefore great. We have not always used these opportunities as well and as wisely as we might, but with respect to the general area of concern of this committee of the Congress, Vanderbilt, I believe, has done well. And no doubt the university's been prompted to do so by governmental interest, inquiries, and directives, and not alone by the challenge of the issues themselves.

My first exposure to discussions in the field of in vitro fertilization came in the late summer of 1978, when President Emmett B. Fields appointed a committee to meet and inquire into the question of whether there were special reasons why the work of Prof. Pierre Soupart, M.D.—now deceased—which was aimed especially at the identification and treatment of problems of human infertility, should not be recommended for governmental support. I chaired that committee and our normal procedures at that time had already been followed, that is, the peer review had occurred. There was an institutional review board which had already reviewed the work and given a green light to Professor Soupart. And the committee that deals with the question of experimentation on human subjects had, I believe, already reviewed the matter. So all the normal procedures had been followed, but the president and the medical people thought that something else might be done.

And so they appointed this committee of citizens and of members of the university community, including people from most of the schools, to meet and discuss this question and give a recommendation in addition to those already received.

Our committee met several times a week for about 5 weeks and concluded that there were a number of serious ethical issues that required to be kept constantly in view as work in this field of medical research proceeded.

We should note that Dr. Soupart had not, I believe, at that time, any intention of doing embryo transfer or the implantation. He was simply fertilizing eggs and studying the whole situation to see what could be learned in respect of problems of human infertility.

But we saw no compelling reason for not affirming both the intentions and the procedures of Professor Soupart. Indeed, the committee recognized in him a person as sensitive to the moral considerations and the need to honor life as anyone could be.

Our committee also recommended that a standing university committee be established to review such questions as those that had confronted us.

Over the succeeding years, similar committees have been called into existence, it having been determined that committees convened ad hoc might do better than a standing committee. The membership on these committees of men and women from the larger Nashville community, who have no formal ties to the university but who have demonstrated ability in sorting out complex ethical questions, has proved immensely valuable, as it did in the case of the first committee.

We have also been helped at Vanderbilt by the creation of a sizable number of seminars and colloquia on the relations of medicine

and law, medicine and theology, medicine and humanistic learning in general. There the smallness of the university, but its full complement of schools, I think, does help us.

The campus climate is, I believe, a good one for the airing of these fundamental questions, questions that are too important to be left to specialists of only a single discipline.

As part of the organization of the center for fertility and reproductive research, an advisory board of members of the community, including several persons from nonmedical parts of the university, was called into existence. I was asked to be a member of that advisory board and I gladly agreed to do so. My 2 years on the board were instructive and challenging.

My special responsibility was to serve on a committee dealing with ethical and theological considerations that faced the center.

Our committee, consisting largely of advisory board members, but also including some persons not formally on the board, met monthly or more frequently, addressing an agenda of issues and examining others that had arisen in the course of its initial organizational work as a committee.

It was immensely impressive to me to see how within a short time such a group of citizens, only one or two of whom were well informed as to the medical and scientific aspects of the work of the center, learned how to work together and to identify where the ethical and theological challenges lay.

Our committee contained one long-time leader in the field of public precollegiate education, two attorneys engaged in civil practice within the State, one theologian, one member of the faculty of the Vanderbilt School of Nursing, and several men and women active in community affairs and particularly concerned with problems of infertility and with family health.

Our most difficult and fascinating task was to prepare for the Board's consideration a set of ethical guidelines for the center to follow. Our committee quizzed the members of the staff regarding such issues as who would avail themselves of the center's services: Would only the wealthy be able to be helped; how the procedures in the center's research and service programs would assure a constant and unmistakable respect for living tissues and for life processes; how far the center would be going into areas where the ethical issues seemed to us not yet adequately explored; and what the center's own professional staff saw to be the most important and difficult issues confronting them. That is, we took it upon ourselves to try to get the staff to say where they felt the ethical pressures lie, as well as to seek to understand what they were doing and intending to do and ourselves bring up ethical matters.

Our committee had to meet often, for fairly short periods of time, and we had to feel our way during the initial sessions. The staff's readiness to share candidly with us their own ethical concerns was extremely valuable to us.

The committee initially developed a long list of concerns, trimmed these down, and prepared a brief but weighty, we thought, set of recommendations for the advisory board to consider. I've brought along copies of some of those materials that can be a part of the record if you would like.

These recommendations, with some modifications, were adopted and have guided the center since that time, along with other matters that have been adopted since I left the membership of the committee.

In my judgment, the procedure for securing community involvement and for the development of guidelines by medical and nonmedical personnel was an excellent one. The issues that are being addressed by the committee of the Congress deserve and indeed demand mechanisms for the sharing of ideas and concerns across the entire community, locally, regionally, and nationally.

It is important for specialist scientific communities to learn, if they do not already know, that such help is available to them from the larger community. And it is important for the larger community to become informed concerning scientific and technological developments and to take a more active role in determining their effect on our society.

My experience with the Center for Fertility and Reproductive Research has been rewarding. I began the work perhaps a bit too much in awe of my medical-specialist colleagues, and therefore perhaps a bit too eager to demonstrate that my own field had something to offer them. But very soon I was being helped by their own penetrating inquiries, their ways of framing ethical and theological issues. And I found them ready to listen and to consider every one of the concerns that our committee brought forth. This partnership, in my judgment, needs to continue and to flourish.

I might just add that I'm convinced that an advisory body like this has great moral suasion and can do a great deal locally to assist in the addressing of issues by the scientific community without setting itself up as a police board, or something of the sort.

And I offer that remark as perhaps a useful one when one thinks of the national picture. There's something one can distinguish between regulatory bodies, which in some areas no doubt one has to have; and advisory bodies with a clout, which, I think, might help us the more in this area.

Mr. GORE. Thank you very much, Dr. Harrelson. We're going to hold up questions until the panel has finished.

[The prepared statement of Mr. Harrelson follows:]

TESTIMONY OF PROFESSOR WALTER HARRELSON, DISTINGUISHED PROFESSOR OF OLD TESTAMENT, VANDERBILT UNIVERSITY DIVINITY SCHOOL, AND FORMER MEMBER OF THE ADVISORY BOARD OF THE CENTER FOR FERTILITY AND REPRODUCTIVE RESEARCH.

Vanderbilt University has the great asset of being a small university with a full complement of graduate and professional schools, located on a spacious but still densely-built campus. The opportunity for the sharing of ideas and problems across the lines of the disciplines and the Schools of the University is great. Unfortunately, we have not always seized this opportunity and made the most of it.

But with respect to the general area of concern of this Committee of the Congress, Vanderbilt has done well, I believe. No doubt, the University has been prompted to do so by governmental interest, inquiries, and directives, and not alone by the challenge of the issues themselves.

My first exposure to discussions in the field of in vitro fertilization came in the late summer of 1978, when President Emmett B. Fields appointed a committee to meet and inquire into the question of whether there were special reasons why the work of Professor Pierre Soupart, M.D. (now deceased), which was aimed especially at the identification and treatment of problems of human infertility, should not be recommended for governmental support. Our normal procedures had been followed already, and Professor Soupart had the green light to proceed; but the officers of the Medical School and President Fields believed that it would be wise to assemble a group of community and University colleagues to review this whole question and make a recommendation to the University administration.

Our committee met several times a week for about five weeks and concluded that there were a number of serious ethical issues that required to

be kept constantly in view as work in this field of medical research proceeded. But we saw no compelling reason for not affirming both the intentions and the procedures of Professor Soupart. Indeed, the Committee recognized in him a person as sensitive to the moral considerations and to the need to honor life as anyone could be. Our committee also recommended that a standing University committee be established to review such questions as those that had confronted us.

Over the succeeding years, similar committees have been called into existence, it having been determined that committees convened ad hoc might do better than a standing committee. The membership on these committees of men and women from the larger Nashville community, who have no formal ties to the University but who have demonstrated ability in sorting out complex ethical questions, has proved immensely valuable, as it did in the case of the first committee on which I served. We have also been helped at Vanderbilt by the creation of a sizeable number of seminars and colloquia on the relations of medicine and law, medicine and theology, medicine and humanistic learning in general. The campus client is, I believe, a good one for the airing of these fundamental questions, questions that are too important to be left to specialists of only a single discipline.

As part of the organization of the Center for Fertility and Reproductive Research, an Advisory Board of members of the community, including several persons from non-medical parts of the University, was called into existence. I was asked to be a member of that Advisory Board, and I gladly agreed to do so. My two years on the Advisory Board were instructive and challenging.

My special responsibility was to serve on a committee dealing with ethical and theological considerations that faced the Center. Our committee,

consisting largely of Advisory Board members but also including some persons not formally on the Board, met monthly or more frequently, addressing an agenda of issues and examining others that had arisen in the course of its initial organizational work as a committee. It was immensely impressive to me to see how, within a short time, such a group of citizens, only one or two of whom were well informed as to the medical and scientific aspects of the work of the Center, learned how to work together and to identify where the ethical and theological challenges lay.

Our committee contained one long-time leader in the field of public pre-collegiate education, one or two attorneys engaged in civil practice within the state, one theologian, one member of the faculty of the Vanderbilt School of Nursing, and several men and women active in community affairs and particularly concerned with problems of infertility and with family health in general.

Our most difficult and fascinating task was to prepare for the Board's consideration a set of ethical guidelines for the Center to follow. Our committee quizzed the members of the staff regarding such issues as who would avail themselves of the Center's services (would only the wealthy be able to be helped?); how the procedures in the Center's research and service programs would ensure a constant and unmistakable respect for living tissues and for life-processes; how far the Center would be going into areas where the ethical issues seemed to us not yet adequately explored; and what the Center's own professional staff saw to be the most important and difficult issues confronting them.

Our committee had to meet often, for fairly short periods of time, and we had to feel our way during the initial sessions. The staff's readiness to share candidly with us their own ethical concerns was extremely valuable to

us. The committee initially developed a long list of concerns, trimmed these down, and prepared a brief but weighty (we thought) set of recommendations for the Advisory Board to consider. These recommendations, with some modifications, were adopted and have guided the Center since that time.

In my judgment, the procedure for securing community involvement and for the development of guidelines by medical and non-medical personnel was an excellent one. The issues that are being addressed by this Committee of the Congress deserve and indeed demand mechanisms for the sharing of ideas and concerns across the entire community, locally, regionally, and nationally. It is important for specialist scientific communities to learn, if they do not already know, that such help is available to them from the larger community. And it is important for the larger community to become better informed concerning scientific and technological developments and to take a more active role in determining their effect on our society.

My experience with the Center for Fertility and Reproductive Research has been rewarding. I began the work perhaps a bit too much in awe of my medical-specialist colleagues, and therefore perhaps a bit too eager to demonstrate that my field has something to offer them. But very soon I was being helped by their own penetrating inquiries, their ways of framing the ethical and theological issues. And I found them ready to listen and to consider every one of the concerns that our committee brought forth. This partnership, in my judgment, needs to continue and to flourish.

Walter Harrelson
Distinguished Professor of Old Testament
Vanderbilt Divinity School
Nashville, TN 37240

Dr. Harrelson received his undergraduate degree from the University of North Carolina, Chapel Hill. Following four years in the US Navy, he received a doctorate in theology from Union Theological Seminary in New York in 1953. He holds honorary degrees from the University of the South (DD, 1974), and Marris Hill College (D. Litt. 1977).

Dr. Harrelson served on the faculty of Andrew Newton Theological School before becoming Dean of the University of Chicago Divinity School in 1955. He has served as Professor and then Distinguished Professor of Old Testament at Vanderbilt University Divinity School since 1960. He served as Dean of the Divinity School from 1967 until 1975, at which time he resigned to resume full-time teaching. He was a Fulbright Research Fellow (1962-1963), a Phi Beta Kappa (1946), and a Fellow of the Society for Values in Education.

His own writings include Jeremiah, Prophet to the Nations (1959), Interpreting the Old Testament (1964, now being revised), From Fertility Cult to Worship (1969, 1970, reissued in 1980), and The Ten Commandments and Human Rights (1980). He contributed the article on worship for the current Encyclopaedia Britannica and has done many other articles and essays for encyclopedias, biblical reference works, and volumes on the Bible and theology. He has been working for several years on Jewish documents of the so-called Intertestamental Period and is assisting in new studies and new critical editions of some of these writings.

He has been for some years on the Standard Bible Committee of the National Council of Churches which is charged to do a revision of the Revised Standard Version of the Bible. Currently he is Vice-Chairman of the Old Testament Section of the translation committee.

Professor Harrelson was ordained as a Baptist minister in 1949. He is active in the American Baptist Churches in the Disciples of Christ fellowship (where his ordination is also recognized) and in ecumenical endeavors of the Churches. He continues his association with the Ecumenical Institute for Advanced Theological Studies in Jerusalem, serving as a member of its Advisory Council.

Dr. Harrelson served as Chairman of the ad hoc Ethics Committee of Vanderbilt University's Institutional Review Board for the initial review of in vitro fertilization and joined the Advisory Board of the Center for Fertility and Reproductive Research in 1981 to chair the Ethics Committee until 1983.

Mr. GORE. Thank you very much, Dr. Harrelson. We're goint to hold up questions until the panel has finished.

We'd like to hear now from Dr. Anne Colston Wentz, professor of obstetrics and gynecology, and director of the division of reproductive endocrinology at Vanderbilt Medical Center. We're delighted to have you here, Dr. Wentz, please proceed.

Dr. WENTZ. Thank you, Congressman Gore, for inviting us to attempt to explain to you how one community has taken on some of the issues and established what we feel is a means of communication.

The Center for Fertility and Reproductive Research [C-FARR] was formed and organized at the Vanderbilt University Medical Center in 1980 for the purpose of bringing together the necessary personnel and facilities for the comprehensive diagnosis and treatment of the infertile couple. Because infertility is itself broad-reaching, and because its therapy might have sociological and philosophical impact upon the community, we asked community leaders with different viewpoints and areas of expertise to meet with medical experts from the Departments of Obstetrics and Gynecology, Urology, Radiology, Psychiatry, and Medicine to assist in developing the organization of our multidisciplinary center.

An advisory board was established as part of the Center for Fertility and Reproductive Research. The advisory board was formed for the purpose of providing assistance and counsel to C-FARR in matters concerning community education, consumer relations, public affairs, law, and legislation, and ethical and theological concerns.

Initially, those community members who had assisted in the development of the center were organized into a 30-member board, with representation from the Vanderbilt Medical Center Administration.

All persons who agreed to serve on the board brought a particular area of expertise to the center, were broadly representative of many different professions, and included consumers and patients, as well as recognized civic and community leaders.

The board was to be advisory to the director of the center, to the chairman of the department of obstetrics and gynecology, and to the vice chancellor for medical affairs on all matters relating to the purposes of the center and its operation.

When formed, the board developed its own bylaws, and established committees dealing with issues of community education, consumer relations, public affairs, law, and legislation, and ethical, and theological concerns.

A nominating committee was established for the purpose of identification of other community members for nomination to the board, and to elect the chairman, vice chairman, and secretary-treasurer of the board.

The bylaws established that board members would have staggered terms, and that committee membership would not be limited to board members, thus allowing resource persons to serve on committees at the discretion of the committee chairman.

Thus, the 30-member board was additionally diversified by having committee membership from outside the board. All appointments to the advisory board were at the invitation of the vice chan-

cellor for medical affairs of the Vanderbilt University Medical Center. Thus, the board was to function in accord with bylaws which detailed the composition of the board, the terms of membership, meetings, officers, committees, and amendments; the board would therefore be a continually evolving entity.

Because of divisional and departmental concerns of the impact of our work, it was agreed that any questionable or controversial areas would be brought before the appropriate committee for planning and decisionmaking purposes. Each committee was given a carefully formulated charge.

The broad charge to the legal/legislative affairs committee was that the committee should advise C-FARR, through the board, of the legal implications of its activities and the potential impact of proposed legislation at all levels which might affect its programs and activities.

In addition, this committee would develop and assist in implementing strategies for dealing with proposed legislation which might have an impact on C-FARR.

The broad charge to the ethical/theological issues committee was that this committee should, in consultation with C-FARR staff and other resource persons, identify the ethical and theological issues arising from C-FARR activities. The committee should develop a process whereby such issues could be examined to the extent necessary to ensure that broad-board recommendations were representative of informed opinion from the community.

Thus, all committees would be expected to gather information as needed and present a formulation in terms of reports and/or recommendations to the full board.

On matters involving policy, the recommendation of the board would then be submitted first to the director of the development of sex and gynecology, and then to the vice chancellor for medical affairs of the Vanderbilt University Medical Center.

On matters involving scientific or medical issues, the recommendation might appropriately first be directed to the institutional review board.

Through these means the board would give direction and guidance to the work of the physicians and scientists of the center, and would also indicate to the administration of the Vanderbilt University Medical Center that a review process had indeed been followed. Thus, this process was anticipated to enhance the credibility of the work of C-FARR.

This process has worked as we intended. For example, the process was used when we initially began to consider beginning an in-vitro-fertilization program, when various issues were examined by various of the committees.

The same process was followed when the area of sex preselection was considered for implementation, and when legal opinion concerning artificial insemination was needed. The process is currently being used as the decision to enter the cryopreservation area is under discussion in several committees.

The committee approach has proved useful in other regards as well. For example, individuals interested in communication have worked to educate the community about the problems of infertility, and about potential solutions to these problems.

The community education committee has organized various means of publicizing currently available technology and spreading the word about support groups for infertile couples such as RESOLVE. Many infertile couples cannot be helped through available medical technology and choose the adoption process.

Board members interested in adoption have worked with our State legislature to improve adoption laws. This group has expanded to be involved with the legal and legislative aspects of infertility problems. Thus, the several committees have interfaced between C-FARR and the community in its largest sense, working in the best interests of both. C-FARR is thus part of the community.

The advisory board has, therefore, served as a valuable resource to Vanderbilt University in the development of policies and procedures. The board has provided feedback to the medical community on the psychological and sociological ramifications of the new technologies available. Through its support, encouragement, and respect, the Vanderbilt University Medical Center has undertaken a leadership role in furthering means whereby guidance and direction can be a two-way street. The advisory board of C-FARR provides a model showing how communication can be established between the medical center and the community.

Again, I appreciate very much the opportunity to testify before you today about our attempts in this area of communication.

[The prepared statement of Dr. Wentz follows:]

TESTIMONY OF DR. ANNE COLSTON WENTZ, PROFESSOR OF OBSTETRICS AND GYNECOLOGY, DIRECTOR OF THE DIVISION OF REPRODUCTIVE ENDOCRINOLOGY, DIRECTOR OF THE CENTER FOR FERTILITY AND REPRODUCTIVE RESEARCH, VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE, TENNESSEE.

The Center for Fertility and Reproductive Research (C-FARR) was formed and organized at the Vanderbilt University Medical Center in 1980, for the purpose of bringing together the necessary personnel and facilities for the comprehensive diagnosis and treatment of the infertile couple. Because infertility is itself broad-reaching, and because its therapy might have sociological and philosophical impact upon the community, we asked community leaders with different viewpoints and areas of expertise to meet with medical experts from the Department of Obstetrics and Gynecology, Urology, Radiology, Psychiatry, and Medicine to assist in developing the organization of our multidisciplinary Center.

An Advisory Board was established as part of the Center for Fertility and Reproductive Research. The Advisory Board was formed for the purpose of providing assistance and counsel to C-FARR in matters concerning community education, consumer relations, public affairs, law and legislation, and ethical and theological concerns. Initially, those community members who had assisted in the development of the Center were organized into a 30-member Board, with representation from the Vanderbilt Medical Center Administration. All persons who agreed to serve on the Board brought a particular area of expertise to the Center, were broadly representative of many different professions, and included consumers and patients, as well as recognized civic and community leaders. The Board was to be advisory to

the Director of the Center, the Chairman of the Department of Obstetrics and Gynecology, and the Vice-Chancellor for Medical Affairs on all matters relating to the purposes of the Center and its operation.

When formed, the Board developed its own By-Laws, and established committees dealing with issues of community education, consumer relations, public affairs, law and legislation, and ethical and theological concerns. A nominating committee was established for the purpose of identification of other community members for nomination to the Board, and to elect the Chairman, Vice-Chairman, and Secretary/Treasurer of the Board. The By-Laws established that Board members would have staggered terms, and that committee membership would not be limited to Board members, thus allowing resource persons to serve on committees at the discretion of the committee chairman. Thus, the 30-member Board was additionally diversified by having committee membership from outside the Board. All appointments to the Advisory Board were at the invitation of the Vice-Chancellor for Medical Affairs of the Vanderbilt University Medical Center. Thus, the Board was to function in accordance with By-Laws which detail the composition of the Board, terms of membership, meetings, officers, committees, and amendments; the Board would therefore be a continually evolving entity.

Because of Divisional and Departmental concerns of the impact of our work, it was agreed that any questionable or controversial areas would be brought before the appropriate committee for planning and decision-making purposes. Each committee was given a carefully formulated charge. The broad charge to the Legal/Legislative Affairs Committee was that the Committee should advise C-FARR, through the Board, of the legal implications of its activities and the potential impact of proposed legislation at all levels which may affect its programs and activities. In addition, this Committee

would develop and assist in implementing strategies for dealing with proposed legislation which might have an impact on C-FARR. The broad charge to the Ethical/Theological Issues Committee was that the Committee should, in consultation with C-FARR staff and other resource persons, identify the ethical and theological issues arising from C-FARR activities. The Committee should develop a process whereby such issues could be examined to the extent necessary to ensure that Board recommendations were representative of informed opinion in the community. Thus, the committees would be expected to gather information as needed and present a formulation in terms of reports and/or recommendations to the full Board. On matters involving policy, the recommendation of the Board would then be submitted to the Vice-Chancellor for Medical Affairs of the Vanderbilt University Medical Center. On matters involving scientific or medical issues, the recommendation might appropriately be directed to the Institutional Review Board. Through these means, the Board would give direction and guidance to the work of the physicians and scientists of the Center, and would also indicate to the Administration of the Vanderbilt University Medical Center that a review process had been followed. Thus, this process was anticipated to enhance the credibility of the work of C-FARR.

This process has worked as we intended. For example, the process was used when we initially began to consider beginning an in vitro fertilization program, when the issues were examined by various of the committees. The same process was followed when the area of sex preselection was considered for implementation, and when legal opinion concerning artificial insemination was needed. The process is currently being used as the decision to enter the area of cryopreservation is under discussion in several committees. The committee approach has proved useful in other

regards. For example, individuals interested in communication have worked to educate the community about the problems of infertility, and potential solutions to these problems. The Community Education committee has organized various means of publicizing currently available technology and spreading the word about support groups for infertile couples such as RESOLVE. Many infertile couples cannot be helped through available medical technology and choose the adoption process. Board members interested in adoption (both personally and professionally) have worked with our State legislature to improve adoption laws. This group has expanded to be involved with the legal and legislative aspects of infertility problems. Thus, the several committees have interfaced between C-FARR and the community in its largest sense, working in the best interests of both. C-FARR is thus part of the community.

The Advisory Board has served as a valuable resource to Vanderbilt University in the development of policies and procedures. The Board has provided feedback to the medical community on the psychological and sociological ramifications of the new technologies available. Through its support, encouragement and respect, the Vanderbilt University Medical Center has undertaken a leadership role in furthering means whereby guidance and direction can be a two-way street. The Advisory Board of C-FARR provides a model showing how communication can be established between the Medical Center and the community.

ANNE COLSTON WENTZ, M.D.
 Division of Reproductive Endocrinology
 Department of Obstetrics and Gynecology
 Vanderbilt University Medical Center
 Nashville, Tennessee 37232

Anne Colston Wentz, M.D., Director of C-FARR, graduated from Western Reserve University School of Medicine in Cleveland, did a medical internship at the University of Maryland Hospital, and a four-year residency in gynecology and obstetrics at the Johns Hopkins Hospital in Baltimore. She then took a fellowship in gynecologic endocrinology-infertility under Dr. Georgeanna Seegar Jones at Johns Hopkins, and afterwards became a full-time faculty member at Johns Hopkins. She was certified by the American Board of Obstetrics and Gynecology in 1973, and by the Sub-specialty Board in Reproductive Endocrinology when this first became available in 1974. In 1977, she took a Professorship at the University of Tennessee Center for the Health Sciences in Memphis, and in 1980, came to Vanderbilt as Professor of Obstetrics and Gynecology, and head of the Division of Reproductive Endocrinology. Under her direction, the Center for Fertility and Reproductive Research was established in late 1980.

Although her primary interest is in patient care, she has responsibility in the areas of teaching, clinical research, and administration. She is also the director of the fellowship training program in gynecologic endocrinology-infertility. Dr. Wentz is the author of more than 80 articles in peer-review journals, has authored 24 book and monograph chapters, is on the editorial board for "Fertility and Sterility," an assistant editor of the "OB-GYN Survey," and an ad hoc reviewer for five or more other journals. She is a member of the NIH Contraceptive Development Branch Advisory Committee and a member of the Scientific Advisory Committee of the Program for Applied Research on Fertility Regulation. She is on the Board of Directors of the American Fertility Society and is also a member of that Society's Women's Council, Journal Committee, and Program Committee. She was a member of the ad hoc Committee on in vitro fertilization which prepared IVF guidelines adopted by the American Fertility Society. She has been an invited lecturer at over 20 national and international scientific sessions over the past two years.

Mr. GORE. Thank you very much.

The final witness on this panel before we go to questions will be Jane Buffalo, a lawyer in Nashville who is chairperson of the legal and legislative affairs committee of the advisory board to C-FARR, or the Center for Fertility and Reproductive Research.

Ms. Buffalo, it's a pleasure to see you here, and we invite you to proceed.

Ms. BUFFALO. Thank you, Congressman Gore.

Although Vanderbilt University's Center for Fertility and Reproductive Research, which is often called C-FARR, offers a wide range of services in its treatment of infertile couples, there can be little doubt some of its activities, as well as that of other clinics that offer similar services, has generated conflicting issues which are not easily resolved.

Before the center began officially functioning, Vanderbilt was aware of the potential for controversy and attempted to establish the mechanism for facing the controversies head-on and resolving them within the community as quickly, honestly, and fairly as possible.

It was decided that an advisory board would be appointed to advise the centers on matters concerning fundraising, financial development, consumer relations, community education, public af-

fairs, law, and legislation, and on ethical, moral, and theological concerns.

This board was to consist of 30 members, the majority of which—which were required to be from the nonmedical professions. Further, the composition of the board was to be broadly representative of the Nashville community.

In accordance with this directive, the original board, as well as subsequent ones, was made up of lawyers, housewives, public relations, and media representatives, music industry personnel, educators, as well as political activists.

The board's work is generally done through the committee process. To further ensure that the pros and cons of each issue are considered, committee chairmen are given the prerogative of selecting additional members for their committees from the Nashville community who are not official members of the advisory board. This procedure has worked quite well and has resulted in some rather thorough and sometimes heated debate.

Although the work of each committee has been significant, it should be observed that Vanderbilt recognizes its commitment and duty to the community through the efforts of two of its committees: first, the community education committee is charged with developing and implementing a program designed to educate professionals and lay persons in the community on the programs and activities of C-FARR.

Second, the ethical/theological issues committee is charged with identifying the ethical and theological issues arising out of the center's activities, and is further charged with developing a process whereby such issues are examined to the extent necessary to ensure that the board's recommendations are representative of informed opinion in the community.

My committee, the legal/legislative affairs committee, monitors legislation at the State and Federal level and reports to the board any significant developments in either legislation or case law which might affect the center's activities.

Further, this committee works with other committees on identifying potential legal issues as well as on the attempted resolution of the issues identified.

It should be observed that the advisory board is as its name indicates, advisory only. Final approval for the actions of the center comes from the Vanderbilt University Medical Center itself, but obviously the recommendations of the advisory board are given substantial consideration in formulation of policy.

The Center for Fertility and Reproductive Research at Vanderbilt has as its ultimate goal to provide the best possible treatment of infertile conditions. In achieving this goal, the center has not, and will not, ignore community concerns.

The mechanisms established to ensure community awareness and involvement have worked quite well over the past few years, and it is believed that this mechanism will prevent the center's staff or the board members from becoming so overly confident or complacent that the community's interests are ignored.

[The prepared statement of Ms. Buffaloe follows:]

TESTIMONY OF JANE J. BUFFALOE, ATTORNEY AT LAW,
CHAIRPERSON, LEGAL/LEGISLATIVE AFFAIRS COMMITTEE OF THE
ADVISORY BOARD TO THE CENTER FOR FERTILITY AND REPRODUCTIVE
RESEAKCH AT VANDERBILT UNIVERSITY MEDICAL CENTER, NASHVILLE,
TENNESSEE:

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Jane Johnson Buffaloe
2006 Lombardy Avenue
Nashville, TN 37215

Ms. Buffaloe graduated from the University of Tennessee and received her Doctor of Jurisprudence from the YMCA Night Law School in Nashville, Tennessee. Prior to establishing a private law practice in Nashville, Ms. Buffaloe worked for Third National Bank, IBM Corporation, and Xerox Corporation.

She has served as a member of the Center for Fertility and Reproductive Research Advisory Board since 1981 and has served as Chairman of the Legal Affairs Committee. In addition, Ms. Buffaloe has been active in the Nashville Bar Association, the Children's House Murtissori Preschool, and the Woodmont Christian Church of Nashville.

Mr. GORE. Thank you very much. There are a number of questions I'd like to ask to you, all three of you.

First of all, Dr. Wentz, who finances the board, and how much does it cost?

Dr. WENTZ. The board per se requires very little financing. Occasionally for a lunch meeting for busy people, the petty cash from my own division of reproductive endocrinology will provide sandwiches and coffee. And it has been an ongoing problem to have the administration of Vanderbilt University pay for the parking. The secretarial aspects are taken care of by recording into my own cassette tape recorder the conversations of the multiple debates. And my secretary, under sometimes considerable protest, will indeed transcribe these minutes.

Beyond what I have addressed, there is no financing for the work of the board. The board is entirely composed of people with a rather remarkable and generous commitment, and that commitment includes time as well as paying for their own parking.

Mr. GORE. Uh-huh. How long do they serve on the board?

Dr. WENTZ. Initially, we had staggered terms of one or 2 years, such that the people on the board would not all rotate off at the same time. At the present time, terms of office are ordinarily for two years unless a special request is made for either a longer term or a shorter term. The chairman of the board is elected and serves for a 1-year term only.

Mr. GORE. Does the board advise patients in terms of disposition of embryos in case of an accident such as occurred in Australia? Has that question ever been addressed?

Dr. WENTZ. The guidelines that the board has established thus far are that all viable embryos are to be transferred back to the donor. The issue of cryopreservation that is currently under consideration is in process, and I have no idea at the present time what the recommendations of the several subcommittees are going to be at the time that they're presented to the full board for the full board's vote.

Mr. GORE. How do you handle—how do you handle the problem of extra embryos in the current process, even without cryopreservation?

Dr. WENTZ. At the present time, we have transferred back to the mother-to-be all viable embryos and, therefore, have not had extra embryos with which to contend.

Mr. GORE. OK. Do your guidelines—are your guidelines essentially the same as the American Fertility Society? I know you served on the committee for that society which drew up its guidelines. Are yours essentially the same, or do they differ?

Dr. WENTZ. The guidelines—the guidelines that the center will ultimately follow in terms of cryopreservation are presently under considerable, and I might add, heated discussion. One of the areas that has received a great deal of attention is the area of a word that you discussed extensively earlier. That word was property.

Mr. GORE. Yes.

Dr. WENTZ. Although the final guidelines have not been submitted to the board for approval or disapproval, I can at least give you the idea that the word property has been changed to primary responsibility.

Mr. GORE. I see.

Dr. WENTZ. Other such changes have occurred in those guidelines and, obviously, the guidelines as initially established by the ad hoc committee for the American Fertility Society have now to be extended to a certain extent to take into account further and new technologies.

Mr. GORE. Now, in practice you give to the donors the responsibility, or leave with the donors the responsibility of deciding what to do with extra embryos. Is that correct?

Dr. WENTZ. This has never been an issue, and will not be an issue until we change our stimulation protocols to the extent that we will get so many eggs——

Mr. GORE. You use them all now?

Dr. WENTZ. Yeah.

Mr. GORE. You use them all, so you don't have excess or extra embryos?

Dr. WENTZ. That is correct. And I think it is perhaps important at this point to state that when we do have a number of cleaved embryos that should potentially be transferred back, that we may not be transferring in the best interests of the patient in terms of ultimate pregnancy rate. We're not doing that patient a benefit if we transfer more than three cleaved embryos, or cleaved conceptuses.

Therefore, at the present time, our guidelines as they are being looked at by the committees considering whether cryopreservation is going to be done at Vanderbilt, are taking into definite consideration whether the ultimate pregnancy rate may be improved by transferring no more than three embryos.

Stated somewhat differently, I, at the present time, wish that cryopreservation were available to us, because I think that the statistics are now beginning to show quite clearly that there may be a lower and not a higher pregnancy rate when more than three, or perhaps four, cleaved embryos are transferred back at one time.

Mr. GORE. And cryopreservation would be a place to put the extras?

Dr. WENTZ. Cryopreservation would not only enable one to transfer the optimum number of embryos——

Mr. GORE. Yes.

Dr. WENTZ [continuing]. But would potentially, then, allow for a subsequent attempt should the first not take as a pregnancy.

Mr. GORE. I see.

Now, what about the question of disposition of those embryos that will be in excess if such a procedure is used at Vanderbilt?

Dr. WENTZ. I have no idea what the guidelines to the scientists and medical people of the center are going to be. These are under consideration and in process at the present time. And, although, obviously, I have my own personal opinions, and I would like to influence the deliberations of these various committees, I have very little effect on what their ultimate guidelines will be.

Mr. GORE. Dr. Harrelson, you wrestled with similar questions in reviewing Dr. Pierre Soupart's work. You came to the conclusion, which I believe you stated in your testimony, that you felt it was all right to conduct experiments——

Mr. HARRELSON. Yes.

Mr. GORE [continuing]. On these embryos.

Mr. HARRELSON. Yes.

Mr. GORE. You want to—as a theologian, do you want to tell me your response to those who are concerned that this violates the dignity of human life, and—and overlooks the—the respect which ought to be afforded to—to a human embryo?

Mr. HARRELSON. Yes. The period of time in which the embryos would be available, the fertilized eggs would be available, for experimentation under Dr. Soupart's program, was the short one. That was one valuable consideration. The evidence that he presented to our committee that offered prospect for learning significant new things about problems of infertility through this research was, I believe, the determining factor for our committee—

Mr. GORE. Which outweighed—

Mr. HARRELSON [continuing]. Which outweighed the other consideration.

I find that we are often in that kind of situation. Now, not just that one does the lesser of two evils, but does the better of two alternatives, both of which have good and evil strangely intermixed. And I think we confront that all along, and the committee apparently thought so too. It indicated that there could very well be proposals coming from the Soupart work that it would want to object to. But at the moment, it saw none that required such objection.

Mr. GORE. Uh-huh.

Ms. Buffaloe, as a lawyer, you have reviewed the arguments in this area. What do you believe are the most difficult dilemmas presented by embryo transfer and by cryopreservation in particular?

Ms. BUFFALOE. From a legal standpoint, I think perhaps the most issue—the major issues concerned is whose are they? Whose—you know, the word property is something that we have hashed back and forth considerably between the Ethics Committee and the Legal/Legislative Affairs.

We think that leads to a lot of other legal questions, such as the responsibility, and by changing the word to primary responsibility, you indicate that perhaps there is a secondary responsibility.

Mr. GORE. Uh-huh.

Ms. BUFFALOE. So, really, what it gets down to is a weighing of the various interests of the parties. Anytime that you have more than one person, or more than one patient involved in a process, then you have to balance the interest of the different parties involved.

We see the issues as being, you know, perhaps—there are all sorts of issues that are side—that come from that central issue. But the operation of the center in and of itself has some specific legal problems that they must address, such as the records retention problem. There are no guidelines that says what sort of records are required to be kept, or who is required to keep them, or how long you are required to keep them, or to whom they should be made available. And we can see this as a potential for litigation in the future. I mean, it has become the very in thing for adoptive children to go back to trace their roots, so to speak. With the present standard—with the lack of standards at the present time requiring any records to be kept, we can see—you know, it—does the univer-

sity and its center have any liability to these prospective parents and to the child-to-be.

The other question that comes from that is the dissemination of the information, the request and the desire for anonymity among the participants in the procedure is very, very persuasive in deciding to—how the records are to be kept, and what—But, again, it gets into the question of, you know, to whom should the information be disseminated. And there are no guidelines. And we see that as an area where there should be some guidelines, and there should be some assistance.

The other perhaps significant issue that is of concern is the idea of consent, informed consent. Do the patients and the people involved in the procedure really and thoroughly understand what it is that they are going through, and are they in such a position, both psychologically and physically, to give an informed consent. And we think that we have to do everything that we can.

There are no perfect questions—there aren't too many legal issues. But all we can do is try to weigh the countervailing issues and come up with the answer that suits, best suits, the community and the majority of the people involved.

Mr. GORE. Uh-huh.

Have you dealt with the question of inheritance rights?

Ms. BUFFALO. We are dealing with the question of inheritance rights. At—presently, again, this gets—this is an area that concerns me as chairman of the legal/legislative committee, is the fact, to begin with, not all the patients at Vanderbilt clinic are from the State of Tennessee. Now, we are primarily concerned, obviously, with the Tennessee laws as they relate to that, and we have considered that. And that we consider it to be—we have not made official recommendations yet to the board, but we are considering the inheritance rights as a part of the overall subject that we are considering at the present time.

But when you're talking about patients that are coming to Vanderbilt, perhaps from the State of Michigan, or from the State of Arizona, or wherever, where we are not in a position to advise them as to their inheritance rights, or lack thereof. We can see where a national advisory committee—and I use the word advisory again—would be very beneficial in that it would be an opportunity to exchange ideas and information that would better assist us in advising the patients at C-FARR.

Mr. GORE. OK.

Dr. Harrelson, have you discussed surrogate motherhood in your deliberations?

Mr. HARRELSON. Yes, we did, and at great length; and got information, as much as we could get, about what people were doing, and what kinds of interests the staff had in this whole development. And we were grateful that the staff of C-FARR did not have in mind this procedure. And so we simply tabled that discussion for a later time, and so we got out of that. And as a matter of fact, many of the issues that we discussed did not really come up. The staff, for example, were perfectly ready to receive couples. And so we didn't have to worry about the question of persons not formally married, or the question of persons who did not believe in marriage, or anything of that sort. That helped us also.

But we did discuss, recognizing that once one begins in this area, then one has to be prepared, not simply to hear what the community currently is objecting to, but what it certainly will get around to object to once it thinks of it.

And so we did try to anticipate: No. 1, what the fundamental moral questions are in and of themselves and; No. 2, what our local community is likely to find an acceptable approach in this area since we recognize that sensitivity to community concerns is a part of the reason for our committee's existence.

Mr. GORE. I see.

Dr. Wentz, the center decided not to get into the area of surrogate motherhood. What about lavage? Have you decided not to get into that also?

Dr. WENTZ. We feel that our in vitro fertilization program is, albeit a small program, but a very successful program, that have not felt the need to add that additional technique to the armamentarium. Therefore, we have not asked the committees to take under consideration the possibility of entering the area of lavage.

I might emphasize that we are a small group. Our nucleus is a very small number of people, and our in vitro fertilization program at the present time requires a great deal of time and expertise. Were we to go out into many more areas at present, I doubt that we would be able to maintain the quality essential for the overall care of the infertile couple.

Mr. GORE. I see.

Ms. Buffalo, have you ever made recommendations that were not accepted in your role on this committee?

Ms. BUFFALOE. I'm certain that I have, and right now I can't think of any major ones that we have. But I know, for instance, in the more in the mechanical procedures such as the consent forms and the—

Mr. GORE. I see.

Ms. BUFFALOE [continuing]. Advising of—things such as that, we have certainly—we're not just a yes board. And another example of that is when the committee was asked to consider the sex preselection techniques, and it was vetoed, you know. So the process does work both ways, it doesn't—just because a certain committee or subcommittee recommends something, it is not automatically approved.

Mr. GORE. Now, who recommended sex selection?

Ms. BUFFALOE. I'll have to refer to Dr. Wentz on who it was that recommended.

Dr. WENTZ. Sex preselection can be used both to select for males and to select for females.

Mr. GORE. Yeah.

Dr. WENTZ. And there are several techniques that are available and used by our group as well as others. The particular issue that we wish to address at our level first and then to take to the Institutional Review Board was the use of a particular technique, the use of an electric current to separate sperm into X on one side and Y on the other.

Mr. GORE. Uh-huh.

Dr. WENTZ. This particular technique was described to our Ethics Committee, it was described to our Legal Committee, and the result

to the board was that from an ethical standpoint sex preselection was perfectly acceptable.

We then went to the Institutional Review Board with the scientific technique, recalling that the Institutional Review Board is not concerned with issues of ethics.

Mr. GORE. Yes.

Dr. WENTZ. And at that level, the Institutional Review Board felt that there had not been sufficient animal experimentation to allow the particular use of the particular electric current to separate X and Y sperm.

Mr. GORE. I see, I see.

Ms. Buffaloe, you described the community concerns about these questions and the need to address them at the community level. In doing so, do you find deliberations in other areas and even other countries helpful to you in addressing these questions?

Ms. BUFFALOE. Definitely so. Not a week goes by, and sometimes not a day goes by, that we aren't bombarded with information that comes through the center, as a matter of fact, reports from various committees around the world and within the United States, of course, Australia and Great Britain, and things such as that.

And then also, our staff at Vanderbilt is recognized in and of itself as being experts in their particular areas and have had occasion to visit other centers and other operations. And as a result, we find the exchange of information to be invaluable. Without it and without—it gives us a starting point from which to develop our guidelines.

Mr. GORE. Since there's such a tremendous difference between State laws and since so many States haven't even begun to address some of these difficult questions, do you think that there is a need for a more comprehensive model law to serve as a guideline for those States who are looking for assistance and advice in venturing into this area?

Ms. BUFFALOE. My personal opinion at this point is that a national model law would be premature because these scientific developments are still continuing, and what we might end up doing is trying to anticipate a lot of things that never come into being.

What I personally—I agree very much with Dr. Harrelson in that a national review advisory board similar to the advisory board established at Vanderbilt but made up of persons all over the United States from the various respective disciplines——

Mr. GORE. Uh-huh.

Ms. BUFFALOE [continuing]. Would be very beneficial. And although it would not be binding, it would give some guidelines to follow.

Mr. GORE. So you agree with the recommendation of our first witness, that we need a national commission to address these questions on a national level?

Ms. BUFFALOE. I would like to with the proviso that it is advisory——

Mr. GORE. Yes.

Ms. BUFFALOE [continuing]. At this point.

Mr. GORE. Very good. OK. Well, several witnesses have spoken in favor of that.

Dr. Wentz, you state that any questionable or controversial issues are brought before the appropriate committee. Who decides whether an issue is controversial or questionable, and decides to refer it to a particular committee?

Dr. WENTZ. All of us have—well, all of us are thinking people, and all of us are concerned physicians and scientists, and all of us have questions. When, in our many weekly meetings, one of us has a question, or cannot decide an issue, or has a hypothetical “what if” to discuss, then we attempt to arrive at some sort of decision at our own level.

But, by and large, the issues are obvious ones. And we send to the various—to the board for designation to the appropriate committee, some question or issue that we feel is important, perhaps once every other month.

The areas that I have mentioned so far have been sent—one of the major areas that will take a great deal of time of the board coming up will be the whole area of artificial insemination and the legal aspects of this.

So, therefore, there are many people involved. We have four or five M.D.'s, two Ph.D's, we have nurses, we have social workers, we have geneticists involved within the group—and all of these will have questions at various times.

Mr. GORE. All right, very good. I could ask a number of other questions but since we have another panel, we're going to have to move on. I want to tell you how impressed I am that you all have used the resources available in Nashville and at Vanderbilt to address these questions in such a responsible and imaginative way.

I started to say earlier that your effort could serve as a model for other institutions addressing these questions but in line with the comments about models in another context, it's clear that not every community has the same assets or resources, and not every university does. But the commitment you have demonstrated certainly should serve as a model, and the diligence with which you have pursued these questions is something that I certainly admire, and something that will have to be emulated around the country if we're going to address these difficult questions responsibly.

Thank you very much for helping us today.

Mr. HARRELSON. Thank you, sir.

Mr. GORE. Our final panel is on the legal problems associated with alternative reproduction technologies, and I'd like to call to the witness stand four people: Prof. Alex Capron, professor of law, ethics and public policy at Georgetown University; Prof. John A. Robertson who is the Marrs McLean professor of law at the University of Texas School of Law at Austin; Ms. Lori Andrews, research attorney with the American Bar Foundation, and author of the recently published book “New Conceptions”; and Prof. George Annas, Utley professor of health law, Boston University School of Public Health in Boston.

We are delighted to have you all four join us today. Without objection, your prepared statements will be included in the record in full. And we will proceed now to hear your testimony, holding questions until you've all completed your testimony.

I guess we will begin with Prof. Alex Capron, professor of law, ethics and public policy at Georgetown. You have been with us on

other occasions on the genetic engineering hearing, genetic therapy, perhaps one other. I might also add to your credentials here that you were the executive director—genetic screening was the other one—you were Executive Director of the President's Commission on Bioethics. I know the formal title is much longer than that, but that's essentially what it was. And we appreciate your help and expertise, Professor Capron, and we'd like to invite you to begin. Please proceed.

STATEMENTS OF ALEXANDER M. CAPRON, PROFESSOR OF LAW, ETHICS AND PUBLIC POLICY, GEORGETOWN UNIVERSITY LAW CENTER; JOHN A. ROBERTSON, PROFESSOR OF LAW, THE UNIVERSITY OF TEXAS AT AUSTIN; LORI B. ANDREWS, RESEARCH ATTORNEY, AMERICAN BAR FOUNDATION; AND GEORGE J. ANNAS, UTLEY PROFESSOR OF HEALTH LAW, BOSTON UNIVERSITY SCHOOLS OF MEDICINE AND PUBLIC HEALTH

Mr. CAPRON. Thank you. It's a pleasure to be here; and I have submitted my statement, and I'll just give you a brief summary of that.

Now, the reminders we've had from the media recently of the currency of these issues and of the conundrums that they raise, you have focused today on embryo transfer. I think that is one reminder of a much broader field, and I'm pleased to see that you are expanding this topic to include those other questions that arise. Part of the indication of the novelty of this subject, seems to me, is the fact that we don't even have a vocabulary to describe many of the relationships that arise: the term surrogate mother, carrying mother, the like is being used.

Dame Warnock, who chaired the committee in Britain about which we've heard, was even struggling to describe the entire field. "Human assisted reproduction" was a phrase that she used in her report. I was puzzled at that because it does seem to me that reproduction is usually humanly assisted. But we are looking for a description of this entire field.

I want to just summarize a few points. The first is that in addition to our society's traditional responses of prohibiting certain things, encouraging, regulating—I think in this case we need to have an additional response which I've termed somewhat awkwardly, the need for creative preservation. That is to say, realizing that when new scientific developments along, which may be bothersome, we cannot simply respond either by throwing up our hands and saying what will be—"what can be done, will be done," and "there's nothing we can do about it, it's going to make fundamental changes which we find troublesome," or trying to prohibit in holding back the sea, which we cannot do in most of these areas.

I do think that if we can identify what the problems we believe will be created, and from the beginning begin to separate out those steps, particularly the therapeutic steps which have advantages for people, that make them justifiable, and then see those other uses of the same techniques which may have disadvantages, and try to talk about ways of educating society, of identifying the values that are in some way threatened, and finding ways of buttressing, and

preserving, enhancing those values and those roles in society, those actions that are important to preserve.

If we don't do this, we are going to be, I think, very upset by certain developments. In my testimony, I mention, for example, one which I chose because it is futuristic, rather than focusing on one of the ones that's closer at hand—suppose that because of a difficulty that a group of women have with carrying a child, despite the fact that they are able to conceive, it were felt by scientists advisable to develop what would be in effect an artificial gestater, with the artificial placenta, and so forth, the total extracorporeal, as we say now, outside the body——

Mr. GORE. Artificial womb.

Mr. CAPRON [continuing]. Gestation—artificial womb.

If that were possible for that purpose, there might be sympathy on the part of many people to the use by a group of people who want to have children to use that device. And although it sounds farfetched, what we're really talking about is something which would, on the one hand, push back the neonatal intense care unit to babies that are now as young as 20-some weeks in gestation who are born prematurely and are able to be sustained, and find ways of sustaining those earlier and earlier into pregnancy. And at the other end be pushing forward the in vitro techniques that you've heard about here. And at some point be able to say we've made a mesh and we can do it all the way through in the clinic, in the laboratory.

Now, if that possibility existed, its greater use, its broader use, to create the hatchery of the brave new world, I think would be regarded by most people as a very disturbing prospect. I think we have to identify why we would regard that as disturbing and how we can contain the impulse to see it used that way, and what particular problems would arise in particular uses. And I suppose here I would agree with what I took to be Professor Grobstein's answer to your question, it's not the technology itself that raises the question, it's the usage: Why is something being done? What ends are being served, and disserved, in a particular process that makes it acceptable, unacceptable, ethical, legal, whatever? And I think that that's something which we have to keep in mind as we look at these new technologies.

Second, I believe that to find that type of basis, as earlier witnesses have suggested to you, if we are looking for a way of having a moral basis for concerted action in a society that is as pluralistic as ours, we need to have a forum through which these issues can be debated that will last longer than these very laudable hearings that you are holding now, and allow the issues to be heard publicly, coverage through the television, in the newspapers, debates broadly held across the country, with some opportunity to further our understanding—not just simply to argue about it, but to come up with some understanding of what the real issues are.

And I would certainly hope that when your colleagues sit down with the members from the other body in conference committee on the NIH bill, which both Houses of the Congress have passed, they will seize the opportunity to craft a body that combines the independence that you, Mr. Chairman, have placed in the Genetic Engineering Commission that grew out of your earlier hearings, with

the broad mandate that the Senate bill gives to the proposed Bioethics Advisory Committee, which is lodged in the Office of Technology Assessment, which I'm afraid it would not have the same opportunity of independence and broad public scrutiny that a Presidential commission could have.

And I know that when we had those hearings back in October, I guess it was, 1982, you asked each of the witnesses over those 3 days, what—and people who came to the table, I think were much more varied, and argumentative positions than you've heard today on this issue, what they thought of such a commission.

And I think you found from all quarters——

Mr. GORE. Unanimity.

Mr. CAPRON [continuing]. Unanimity. And I think you will find again the notion of an advisory body to study——

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. And make recommendations without regulatory power; that this is the type of issue that needs it. We cannot simply take the Warnock report, as valuable as it is, and use it as a blueprint here. We have a different society; we have a different legal system, with our State and Federal division, and so forth. But I think that's an indication that a broadly based body can, over a several year period, come up with some very valuable recommendations.

Mr. GORE. Well, if I may interject there—there seems to be an emerging consensus that we urgently need a national commission on human genetic technologies to cover not only the genetic engineering and genetic therapy questions explored earlier, but also the alternative reproductive technologies, so that we as a Nation can address these very difficult bioethical questions, and come to some sensible resolution of those questions.

I will urge my colleagues in the House and Senate to adopt that measure. It is now pending; we passed it in the House, and a very different weaker version was passed in the Senate. Perhaps we can, as a result of these hearings, get such a measure out of the conference committee.

Mr. CAPRON. I think that would be a very valuable outcome of these hearings these 2 days, is to remind your colleagues that that kind of a compromise, really building on some of the strengths of both proposals, would offer us an opportunity to address some of these issues.

I tried as a third point to set out in a table in my presentation, and then here on the board, some of the different alternatives. And I don't want to go through these now because of time, but if it would be useful we can use this as a basis for discussion.

One of the reasons I wanted to do that was—and if you look (indicating), the first thing there is ordinary, old-fashioned reproduction, where the M stands for the Mr. and Mrs. married couple, and X being female, Y being male. They are the source of the genetic material, fertilization occurs through natural intercourse, gestation occurs in Mrs. M, and Mr. and Mrs. M plan to be the parents, the social parents of that child.

One of the reasons to mention that is that the first three alternatives all address situations arising within the family, where there's a therapeutic desire either in the case of artificial insemination

with the husband's sperm because of some problem either in the union, or in the quality or quantity of the sperm, or with in vitro fertilization perhaps with a blocked fallopian tube with the woman.

And these are the kinds of, I think, the initial impulse behind each of those techniques was within that context. It's when one begins to add in other parties—the fourth alternative there, where you have the donor, as we say—actually, vendor would be a better word—of the sperm as the source of the male genetic material, and so forth, one begins to add complications.

Recently, of course, with freezing, even the first two alternatives, where the artificial insemination can be done with frozen sperm from the husband, or where the in vitro process could lead to a frozen zygote, or embryo, or whatever you want to call it, here, too, we see even in the marriage situation where you don't have any outside parties other than the physician, we can have complications.

But as we go down this list and begin combining different things to the point, of course—the ninth alternative that's listed there, you have in vitro fertilization using a donor sperm and that, of course, was the situation that the Rioses were in——

Mr. GORE. Yes.

Mr. CAPRON [continuing]. The California couple that went to Melbourne for that procedure, and then the in vitro fertilization leading to the frozen embryo.

The final point is simply that one could indeed have all five different parents, as it were, in the process, be different people; an egg and sperm from one and two; another woman, three, being the gestator; and then four or five being the parents who will take the child on birth and raise it. And this, I think, indicates the kind of complications that we have found ourselves with.

In looking at these issues, I would divide the issues into two groupings. And from what I know of my colleagues here, I think that we would probably be in agreement; one set of issues involves the extracor—those that arise from the fact that human germinal material is outside the body and is subject to manipulation. And the second set of issues arises from this potential division of parentage that did not previously exist among the genetic source, the gestational mother, and the social parents.

The first group of issues includes questions such as those about the arrangements, if any, that should govern ownership of germinal material: Should this be left to private agreements among people, or are there some good public policies for limiting people's freedom legally to transfer control of such material with or without financial compensation?

My own sense is that the terminology of ownership is not particularly helpful in this area, and that we really need to develop a vocabulary representing the different interests that people have and, consequently, the rights that they might have over the material.

But that even in the past, when we've spoken of dead bodies, the law traditionally denied the notion that there was an ownership interest in the dead body, but it did recognize other sorts of interests that people had, and obligations they had toward dead bodies. And I would certainly think that we are going to have to do the same as

some recent court cases, both here and abroad, have indicated about germinal material.

Likewise, the question: What would happen with germinal material—if a person who has entered into some kind of an agreement dies, or if the agreement, the private agreement, breaks down. For example, if the Rioses, rather than dying in a plane crash had found themselves in a divorce situation, and each of them said: "We want those two frozen embryos," or, rather, had said, "I don't want them, but I don't want you to use them." What obligations do the people who are holding the embryos have toward the embryos and then toward these two parties with whom they had an agreement previously?

The second set of issues which arise when the people who provide the child's genetic heritage or who carried during pregnancy are not going to be the ones who act as the social parents, are at least as complex as those involved in the extracorporeal holding of the germinal material.

Plainly, this issue is not a new issue, since it already existed in the adoption situation. And, indeed, one can look to some of the rules that have been developed around adoption and artificial insemination by donor. But, unfortunately, those I do not think form a consistent pattern. They really are a patchwork of statutes and court decisions. Almost half the States now have statutes on artificial insemination by donor, and it is true that most of them are consistent in saying that a husband who consents in advance to his wife's insemination by donor sperm is to be regarded as the legit—the father of that child is to be regarded as his legitimate offspring. And, likewise, that the donor does not have any rights or obligations toward the child. But that is true only in the States that have those statutes, and even there there are variations.

Moreover, there are a great many questions that those statutes don't answer. Should artificial insemination by donor be available as a matter of right to people who are not married, including single women? May a State restrict the legal benefits of its AID law to inseminations which are performed by physicians? And like a private adoption, can you have a private nonmedically supervised AID and then take whatever benefits the law gives?

What are the physician's obligations in screening the donor of the genetic material for genetic or infectious diseases? And are the obligations of sperm banks, which have frozen sperm, any greater because of the greater opportunity they would have? What records should be kept and who should have the access to them, and for what purposes?

Unfortunately, the law in this area has contributed, I think, to the confusion, because the early legal cases which suggested that adultery was the proper way to characterize artificial insemination by donor, and that the child might be illegitimate, and so forth, led many physicians and—indeed, the studies have shown a majority or more of physicians—not to keep records that would be useful in tracking down who the father was, because they have not wanted that to happen; they were afraid it could happen; and the best way to avoid it was just not to keep records.

If that's the case, then important genetic information that might arise on either side of the relationship, something that turns up in

the child or in the father after the insemination has occurred, would not be traceable, and there would be just no way of knowing it.

Moreover, if there are any interests beyond that, psychological interests or financial interests, that ought to flow, those too would be not possible of being followed through; to say nothing of the recordkeeping that society might want to engage in.

We don't even know how many inseminations there are. One hears estimates from fewer than 10,000 to up to 20,000 of births each year with artificial insemination by donor. And I think everybody who gives you an estimate like that is just repeating what else they've read from somebody else. There isn't a solid basis for knowing.

Unfortunately, with the long list of questions that could be raised in this area—no sooner had the States begun to deal with these than, by legislation, than the new reproductive technologies, which we're focusing on today, started coming forward. And they, if anything, threw further confusion in, even to the point that some of the legislation which had been passed for AID, are almost nonsensical in the situation with some of the other technologies.

For example, if a husband of a woman who is entering into a surrogate relationship, a surrogate parenting agreement, with someone else, does not object to the insemination, he would be regarded as the father, because there would then be a situation comparable to artificial insemination by donor. The father-to-be of the child, who intends to take the child away, would in effect be in the donor situation.

And, indeed, the court cases that have arisen around this, have indicated that lawyers, in anticipation of that, have had the husbands of such surrogates fill out statements saying, "I do not consent."

Now, you can imagine the complications that that could lead to in their own relationship later on, to say nothing of the questions that arise about the novel sorts of family relationships that could exist: What is the relationship, for example, between the child born by a surrogate relationship and the other children born of the surrogate mother in her own family?

Now, the intent is that they should have not social relationship. But if the other children are already existing and know that their mother is pregnant, and has gone to the hospital to have a baby, and the baby didn't die, the baby went away—they know that they have a half sibling somewhere. And what is—what is, or ought to be, if any, their relationship with that person?

There are, after all, situations where there would be either financially, psychological, or potentially even medical interests in knowing where that child is, and in having contact with that child.

I don't think that we have done enough to focus on what seems to me to be the group that ought to concern us the most, who are the offspring. So often, both in the court cases that have arisen and in most of the literature, the focus has been on the adults because, after all, it is the adults who want to have children, who are the stimulus for the activity in this area.

But I think we have to remember—and I don't say this in criticism of the physicians or the parents who are involved—but I think

we do have to remember as a society, that as we are designing our rules, that ought to be our major objective: is protecting the welfare and interests of those children.

To summarize, then, I have a number of recommendations. The first is that we do have established the kind of multidisciplinary body that we have spoken of.

The second is that the National Conference of Commissioners on Uniform State Laws establish a committee to review legislation in this area. And I've talked to them recently, and they say that they do intend to do this now.

The third is, as I've mentioned, that our primary objective in the law be to protect the interests of the children.

Some of my copanelists may disagree with a few of these points and make for an interesting discussion.

I believe that such a law should include a requirement of adequate genetic and other medical screening of all donors of germinal material; that it have provision for confidential records be kept of the identity of all donors; that there be limitations on the number of offspring in—that any one donor of genetic material be used for; that there be restrictions on the use of frozen germinal material after the death of an identified person from whom the material was derived; and that there be explicit rules about the financial and other obligations of those who use the new techniques, even when the process or results do not turn out as anticipated; and that all of these be aimed at ensuring each child will have a family to care for it.

I also recommend that the law allow—that the law follow the precedent already set by the prohibitions on baby selling, and discourage the commercialization of the reproductive techniques that occur when payments are made for eggs, sperm, or embryos or, I might add, or uteruses, I suppose.

Finally, that steps be taken at the State and Federal level to clarify the status of in vitro fertilization and other forms of extracorporeal manipulation of germinal material—specifically:

That the Secretary of Health and Human Services should act, one way or the other, at least, on the May 1979 Report of the Ethics Advisory Board, which has sat on the desk of four successive Secretaries, gathering dust; and should appoint a new Ethics Advisory Board to review research activities that involve the manipulation of eggs, sperm, and embryos, so that these activities could once again, where appropriate, qualify for Federal support; and that State laws on fetal research should be clarified so that they will not chill research or service activities using human eggs and sperm, provided that such activities are in accord with accepted professional and governmental standards and procedures regarding safety, justified need, and so forth.

As usual, it's a pleasure to be here, and I look forward to your questions.

[The prepared statement of Mr. Capron follows:]

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August 10, 1984

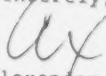
202-624-8327

Ms. Nancy Richards
Subcommittee on Investigations
and Oversight
822 House Annex #1
300 New Jersey Avenue, S.E.
Washington, D.C. 20515

Dear Nancy:

Enclosed please find a typescript copy of my testimony of August 8, for use of the Subcommittee in producing the published version of the material presented at the hearings. This copy corrects several typographical errors I noticed in the copy circulated at the hearing.

Sincerely,



Alexander M. Capron

AMC:lcb

Enclosure

THE NEW REPRODUCTIVE POSSIBILITIES: SEEKING A
MORAL BASIS FOR CONCERTED ACTION IN A PLURALISTIC SOCIETY

Testimony by

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in Hearings on

HUMAN EMBRYO TRANSFER

before the

Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. HOUSE OF REPRESENTATIVES

August 8, 1984

Mr. Chairman, it is a pleasure to be asked to testify once again before your committee. The subject you have chosen to investigate today and tomorrow is one of great importance, and you are to be commended for your willingness to address it. As the media have recently reminded all Americans, biomedical capabilities are being developed in this country and around the world that present us with unfamiliar possibilities in human reproduction, from which flow unprecedented ethical, social and legal issues.

The transfer of a human embryo from one woman to another is one such possibility, though far from the only one. These hearings provide an opportunity for a public examination of the full range of developments in reproduction--from artificial insemination through in vitro fertilization to freezing and banking of sperm, eggs and embryos.

THE NOVELTY OF THE FIELD

Although some of the issues presented have been examined by judges, legislators, and scholars over the past several decades, they remain far from being resolved. Indeed, many of the new reproductive possibilities remain so novel that terms are lacking to describe the human relationships they can create. For example:

- o what does one call the woman who bears a child conceived from another woman's egg? Is she the "carrying mother?" (as the British say)? Or the "gestational mother" (which might be a better reminder of the active--and very important--developmental process in which she is an essential participant)?
- o should this term vary depending on whether the woman intends to keep the child or to give it up?
- o why is a woman who bears a child that she plans to surrender on birth to another couple called a "surrogate mother"?
- o how does one describe the relationship between the husband of a surrogate mother (who has been inseminated by another man's sperm) and the resulting child? Or the relationship between that child and other children born to the surrogate mother?

In fact, I'm not even sure we know what to call the area under inquiry. Dame Mary Warnock, who chaired the recent British committee of inquiry, described it as "the field of human assisted reproduction." Although that description may seem amusing--since, after all, human reproduction has always involved some "human assistance" (at least for those not divinely created)--I am sympathetic to the Warnock Committee's difficulty in finding the right term. To speak of "new reproductive technologies" (as that committee does at other points) is mostly correct, but some of the methods used are not very new (artificial insemination, for example) nor very "technological" (in the sense of requiring expert assistance or complicated devices).

I would also resist lumping all the methods we're discussing under the heading "nonnatural reproduction." For many people such terminology connotes practices that are morally illicit. Furthermore, that wording is not very helpful even descriptively, since all of medicine--including the attendance of physicians, midwives and nurses at uncomplicated deliveries--is in some sense "nonnatural." What is the essential aspect of reproduction that must be "natural"? Even in a petri dish, the union of human sperm and egg is an event that follows the laws of nature and that (with further effort) may result in the birth of a "normal" human being.

More significant than the lack of a sensible, agreed upon vocabulary to describe this field and its constituent techniques and participants is the absence of any mechanism in this country to examine the social, ethical and legal implications, to facilitate thoughtful public discussion, and to suggest coherent proposals for public policy, including recognition of the sphere that ought to be a matter for individual conscience and choice.

TRADITIONAL FORMS OF SOCIAL RESPONSE TO CHANGE

Before going further this afternoon, in describing what I see as some of the particular problems that have already emerged, I want to suggest a framework for our discussion of the issues. Whenever serious issues are raised about an activity, especially a rapidly developing field of science, society can respond in

several different ways. Sometimes, the danger presented by the activity may seem grave enough to call a halt to it--in other words, to PROHIBIT its use. This in turn may mean a TEMPORARY MORATORIUM to allow a process of assessment to take place (e.g., the suspension of certain genetic engineering experiments a decade ago voluntarily imposed by the researchers themselves) or a PERMANENT BAN (subject, perhaps, to later review, but intended as permanent at the time enacted). Most often, society chooses to PERMIT rather than prohibit new scientific capabilities. Permission itself can have many aspects--the activity can be PROMOTED, REGULATED, DISCOURAGED or TOLERATED.

All of these alternative social responses are sure to be suggested for the reproductive methods that are the subject of these hearings. The Warnock Committee, for example, has already recommended that the British government take a number of steps, including:

PROHIBITION

impose a PERMANENT BAN on agencies that exist to recruit women for surrogate pregnancies;

place a TEMPORARY MORATORIUM on embryo donation by lavage;

PERMISSION

PROMOTE the use of counseling for the participants in human assisted reproduction;

REGULATE, through the establishment of a "licensing body," reproductive research and most services;

DISCOURAGE payments (beyond expenses) to semen
"donors"; and

by implication, TOLERATE other practices.

Plainly, this does not begin to exhaust the points put forward by the Warnock Committee nor the responses that a society might have. In our own country, with its greater cultural heterogeneity, explicit constitutional protections of free choice (now often described in terms of "a right of privacy"), and division of authority between state and federal governments, I do not believe that the Warnock Committee's recommendations provide a blueprint for Congressional action at this time. Yet since the expiration--almost one-and-a-half years ago--of the legislation authorizing the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, we have no governmental body charged with reviewing such issues.

THE NEED FOR A NEW RESPONSE: CREATIVE PRESERVATION

This is particularly unfortunate because, as the present topic makes clear, we need to move beyond the range of societal responses that I've just reviewed if we are to deal appropriately with the issues posed. Putting aside for the moment the intense and by now very politicized debate on abortion, I think most Americans would agree that we have a strong tradition in this country--and one that deserves to be respected--of regarding questions of reproduction and family life as private matters,

into which agents of the government should intervene seldom and only for compelling reasons (such as to protect a defenseless person against grave injury). Depending on the biomedical methods in question, prohibition or even regulation may be very difficult if not impossible if the state is going to avoid becoming involved in the most intimate aspects of its citizens' lives.

When it comes to framing public policy, our society may thus decide to tolerate certain things that we regard as undesirable (or at least have consequences that a great many people find personally unacceptable), because any attempt to interfere in their use would intrude the state too deeply into our lives and would seriously threaten personal and family autonomy and diversity. It is here, however, that we need something more than the binary Prohibit/Permit approach.

If we can anticipate that certain biomedical developments--which we do not want to prohibit and which may even provide benefits to some people--may nonetheless undermine basic values or weaken important roles, we ought to make such challenges explicit and then mount the necessary efforts to counteract their undesirable effects. Such an effort might be termed "creative preservation"--signifying a positive and original effort to enhance important values and relationships, rather than either a negative (and probably futile) attempt to forestall use of the biomedical technique or a resigned acquiescence in its undesirable changes.

For example, as I will explain in moment, it seems doubtful that so-called surrogate mother arrangements can be effectively prevented. Recognizing their inevitability, one response might be to bring them within the ambit of the regulations that are applied to adoption, artificial insemination by "donor" (AID), and so forth. If, on the other hand, society decided that such a step would imply approval--and would even encourage--a practice that ought not to occur, it might instead launch an educational campaign designed not only to discourage the practice but to remedy its broader ramifications, including such harmful effects as fostering an attitude that children are commodities to be obtained to satisfy the wishes of adults.

One of the main points I want to emphasize today is the importance of our adopting efforts of the latter sort in appropriate circumstances. It is obvious that the new reproductive possibilities are going to stir up a great deal of passion. With that will certainly come calls for government intervention to stop what some people will regard as pernicious changes in traditional conceptions of human beings, families and society. Some of these concerns may well be justified (e.g., attempts to create "viable" human hybrids with other species) and may persuade policy makers of the need for prohibitions, which can be framed in ways that will avoid any constitutional problems. When such prohibitions are neither justified nor possible, however, I do not believe that we are just left to

say--with a shrug of the shoulders--that "since what can be done, will be done, we must resign ourselves to the undesirable changes that may flow from the uses of new biomedical capabilities."

The "creative preservation" approach is particularly necessary in the biomedical field because a large part of the drive behind the development of new technologies comes from the felt needs of patients (even if some other people might label those "needs" as mere "wants"). This aspect makes it much more difficult to oppose the development of the technique--for in doing so society would not merely be closing off an avenue of scientific exploration (which many--but far from all--people might also regard as a serious mistake) but preventing people from obtaining the treatment they desire (in this case, treatment of infertility). To take a futuristic example: suppose that the problem certain women have in carrying a baby to term could be remedied by means of sustaining a fetus with an artificial placenta, in an "extracorporeal gestator." (This notion ought not to seem too far-fetched, since it involves merely extending back earlier and earlier into pregnancy the capabilities of the neonatal intensive care unit, until they reach the point at which embryos can be supported in an incubator following in vitro fertilization.) In the individual case, such a medical capability may raise only those questions that always arise in human research, especially when the subject of research is incapable of giving consent. But on a societal level, the

capability could have another impact: rather than treating a few cases of woman unable to carry to term, such devices could form the basis of the "Hatchery" of the brave new world. I, for one, would feel much more able to evaluate the prospect of an extracorporeal gestator if I knew we had means to evaluate the harm that could occur through its wider use and to help people avoid the impulse to put it to other uses.

In sum, I believe that we must be more creative--and more positive--in our social responses, to preserve those things that we value in the face of scientific and medical developments. To find a moral basis for concerted action in a pluralistic society--from prohibition to education to permission--we need a forum for studying, debating and clarifying the issues and options. I certainly hope that when your colleagues sit down with the members from the Senate in the conference committee on the NIH bill, they will seize the opportunity to craft a body that combines the independence that you, Mr. Chairman, envision for the proposed presidential commission on human genetic engineering and the broad mandate that the Senate bill gives to the proposed bioethics advisory committee in the Office of Technology Assessment.

TREATING CLINICAL PROBLEMS CREATES NEW ONES FOR ETHICS AND LAW

Although many people think of physicians and other biomedical scientists as problem-solvers, it sometimes seems as though these folks spend their time purposefully making our world

more complicated. Of course, that is a mistaken impression, but it is true that procedures developed to respond to the perceived needs of patients--to restore functioning or enhance well-being--can also be used in ways that are more problematic than first intended. This effect is notable in the field of human reproduction.

In the figure below, I have set forth various forms of reproduction, beginning with the traditional form. The "X" stands for the female, the "Y" for the male. The subscript "M" stands for Mr. & Mrs. Married. One should note here, at the outset, that if the M's were replaced by Ms. A and Mr. B, one would have "normal" reproduction outside of marriage. (In what follows I will not rehearse all the changes of this sort, but the potential for complicating matters, depending on the legal status of the people involved is obviously immense.)

Sometimes conception is difficult because of reduced male fertility (e.g., low sperm count); in such a case, artificial insemination (AI) could be employed, to permit the husband's sperm to be concentrated. This method--#2 in the Figure-- is also useful in other circumstances, as when the wife has certain problems or when, in anticipation of a subsequent fertility problem, a man with normal sperm has stored frozen semen samples in a "sperm bank." Again, this method involves only the M's biologically--though now, of course, a physician is also intimately involved.

FIGURE: REPRODUCTIVE POSSIBILITIES

Genetic Source	Fertilization	Gestation	Social Parents
#1 X _M & Y _M	Natural	M	M & M
#2 X _M & Y _M	AI	M	M & M
#3 X _M & Y _M	IVF	M	M & M
#4 X _M & Y _D	AI	M	M & M
#5A X _D & Y _M	IVF	M	M & M
#5B X _D & Y _M	AI & embryo flushing	M	N & M
#6 X _D & Y _M	AI	D	M & M
#7A X _M & Y _M	Natural or AI,w/ embryo flushing	D	M & M
#7B X _M & Y _M	IVF	D	M & M
#8 X _D & Y _D	Natural, AI or IVF	D	M & M
#9 X _M & Y _D	IVF	M	M & M
#10 X ₁ & Y ₂	IVF or Natural/AI w/ embryo flushing	3	4 & 5

X = female
 Y = male
 D = Donor

M = Mr. or Mrs. Married
 AI = artificial insemination
 IVF = in vitro fertilization

Another medical development, this one aimed primarily at female fertility problems (i.e., blocked Fallopian tubes), is in vitro fertilization (IVF)--that is, the creation of the misnamed "Test Tube Baby," misnamed because the glass (vitro in Latin) involved is a petri dish (not a test tube) and because the fertilized egg only stays in the dish a short time and does not

gestate there into a "baby." Since the birth of Louise Brown six years ago, something like 1000 babies have been born after IVF and reimplantation in their mothers, as shown in #3.

The situation gets more complicated as new people are brought into the picture. In #4, a donor ("D") is the source of the sperm, a step that could be employed when the husband appears to be infertile or carries a harmful genetic condition. (The term "donor" is customary although a misnomer, because the sperm is usually purchased.) As a biological matter, fertilization could take place through sexual intercourse, but for moral and psychological reasons insemination is usually performed artificially by a physician (although the biological similarity to adultery was enough to cause courts to so describe the method--usually termed AID, for artificial insemination by donor--when the first cases arose.) Typically, the donor is selected by the physician and his identity is not revealed.

If the situation is reversed and the wife either has no viable eggs or poses a genetic risk to potential offspring, the germinal material could be obtained from a donor woman; this would also be the case if the woman were unable (or unwilling?) to undergo a laparoscopy--a surgical procedure used to obtain the eggs for IVF. Just as #4 is a variation on #2 by the addition of a donor, so this fifth method is a variation on the third. In this case, there are two alternatives. #5A involves the surgical removal of eggs from a donor and their fertilization in vitro by

Mr. M's sperm, after which some number will be placed in Mrs. M's uterus, in the hope that one or more will implant and develop normally. #5B is a newer technique in which fertilization occurs in the donor woman through artificial insemination by Mr. M's sperm; prior to implantation, the embryo is flushed out and transferred to Mrs. M. While this method introduces some complexities, it avoids the need for laparoscopy.

If Mrs. M's problems go beyond having no viable ova and include factors that make it dangerous or impossible for her to bear a child--or, perhaps, if she is simply unwilling to go through a pregnancy--but desires to have a child fathered by her husband, a "surrogate mother" might be employed, as shown in #6. Another form of "borrowed womb" might be used when the woman has healthy eggs but cannot (or does not want to) carry to term. These cases, ##7A and 7B, parallel the fifth situation, but the "donor" woman appears in the Gestation column rather than the Genetic Source column.

Finally, of course, a couple with fertility problems might turn to adoption to become the social parents of a child born to a woman other than the wife, from germinal material that came from that (or yet another) woman and a man other than the husband (#8). Many more lines could be added to our chart, since there are many further combinations of problems or of therapeutic rationales that might seem to justify variations. For example, #3 could be combined with #4--so that IVF would take place with

donor semen (for a woman with block tubes and a husband with sperm problems), as seen in #9. Furthermore, not all the donors need to be the same--as shown in #10, five people could be involved as "parents" to a child. (One further complication--the use of a nucleus from one egg being placed into another, enucleated egg, so that the germinal material would actually come from two women--has neither been attempted with, nor to the best of my knowledge even been suggested for, human beings.)

Additional complexity is added when the germinal material is preserved. About 15% of artificial inseminations, for example, use frozen semen, and attempts are being made to freeze ova as well. Such methods not only open the possibility of greater "selectivity" (as contrasted with the use of fresh semen, for example, when a physician would typically call on the "donors" most readily at hand, namely male medical students), but may also preserve germinal material beyond the lifetime of its source. The potential complications are increased even further when--in order to make best use of the eggs harvested and fertilized and to have the woman's uterus in the best condition to receive the embryo for implantation--embryos (actually zygotes, an earlier stage) are frozen and held for subsequent implantation. The death last year of a California woman, Elsa Rios, whose fertilized ova are in a freezer tank in Melbourne, Australia, has alerted us to the connundra that these new reproductive possibilities can raise.

ORGANIZING THE ISSUES RAISED BY REPRODUCTIVE MANIPULATION

In light of this survey of reproductive possibilities, I believe it will be helpful to divide the issues raised by the various means of manipulating human reproduction into two major groups: (1) those issues that arise from extracorporeal manipulation of human germinal material, and (2) those issues that arise from the separation of genetic, gestational and social/legal parental roles. Of course, many of the same techniques give rise to behind both sets of issues, but I find it more useful to approach the subject by distinguishing among the uses of the techniques.

1. Germinal Material Outside the Human Body

The first set of concerns are presented by the ability to obtain, manipulate and preserve human germinal material outside the human body. The techniques include: (a) collecting semen from men and either using it immediately for in vivo and in vitro fertilization or freezing it for later use; (b) surgical removal of eggs, which can then be used for in vitro fertilization or can be stored; and (c) uterine lavage, to remove a fertilized egg. These methods have in common that the germinal material is possessed outside the body, its traditional site. This new location not only opens up the possibility for manipulation (and the risk of injury) but also raises novel issues about control since the material is no longer a part of the person in whom it

originated but is usually controlled by a biomedical scientist or practitioner. These developments raise many issues, such as

- o should arrangements about the "ownership" of germinal material be left to private agreements--or are there good public policy reasons for limiting people's freedom legally to transfer control of such material, with or without financial compensation?
- o what should happen to germinal material when the person from whom it was obtained fails to specify its disposition prior to dying or becoming incompetent?
- o what should happen when a private agreement breaks down (as during a divorce)?
- o should the answers to these questions differ for eggs, sperm, and fertilized eggs (zygotes/embryos)?
- o what is the legal and moral status of an embryo in the laboratory prior to implantation, and how does that change from minute-to-minute or day-to-day as it develops?

In many ways it is remarkable that the technology has gotten so far along without any very satisfactory resolution of fairly basic issues of this sort. One body of judicial opinions that is likely to be turned to for guidance--the Supreme Court's decisions in the contraception/abortion area--seems to me to offer only equivocal assistance, especially on the difficult issue of the status of embryos outside the body, which is a matter of importance in deciding about the legitimacy of research, about the obligations (if any) to implant embryos, and so forth. The Supreme Court's decisions, especially Roe v. Wade, can certainly be read to hold that a fetus is not a person;

therefore, an embryo--an earlier stage of development--would also not be a person in the legal sense of a being entitled to the law's equal respect and protection. Conversely, the Court's decisions can be read to hold merely that as between a woman and the fetus she is carrying, the former's rights are superior--though the latter also has rights and interests (short of full-blown personhood).

2. Separation of Genetic, Gestational and Social Parenthood

The second set of issues--which arise when the people who provide a child's genetic heritage or who carry it during pregnancy are not the ones who serve as its social parents--are at least as complex and unresolved as the issues just surveyed. Plainly, they need not involve any human manipulation of the reproductive process; adoption, for example, is not a "new technology." But the burgeoning biomedical developments of recent years present a much greater array of issues than those raised by ordinary adoption (which is, incidentally, not without problems itself).

Unlike the first set of issues, there is a good deal of law that might appear to be directly relevant to the questions raised by the separation of biological and social parenthood. Most important are the state laws governing adoption, particularly those that provide for means of supervising the process (including judicial oversight), confidentiality of records, and protection of the interests of children. Yet strains appear even

in this area--such as the exodus of many couples from the official screening process because of the storage of "adoptable" babies and of the long and arduous selection process, and the challenges to confidentiality rules mounted by adopted children who want to learn their natural parents' identities.

As these problems were coming to the fore over the past decade, the states were finally getting around to addressing the additional issues raised by AID. The law created by judicial decisions in this field over the past 35 years has been a patchwork of rules that are at best inconsistent--and generally do not provide a sensible basis for public policy. Nearly half the states now have some legislation on AID. These statutes typically establish that an AID child is the legitimate offspring of a man and his wife, provided that he has consented to the insemination, and remove any parental obligations from the shoulders of the sperm "donor" (who is usually actually a "vendor," paid \$25-100 per ejaculate). This legislation, however, does not begin to address many of the issues raised by AID, such as:

- o should AID be available to people who are not married, including single women?
- o may a state restrict the legal benefits of its AID law to inseminations performed by physicians?
- o what are a physician's obligations--in screening the donor for genetic or infectious diseases? are the obligations of "sperm banks" (which hold frozen semen) any different?

- o what records should be kept, and who should have access to them for what purposes and when?
- o should a child born by AID have any greater right to know the name of his or her genetic father when the donation was not anonymous (i.e., was known to the mother)?
- o what about other rights--such as financial support or a claim on the estate of the donor?
- o reciprocally, ought sperm donors to have any claim on their "children," from an opportunity to learn a child's identity to financial support to a first-refusal right on adoption if the parents are unable to care for the child?
- o may a person (or sperm bank) who has custody of sperm sell it, with or without the explicit permission of the person from whom it came (who might by then be dead), and with or without publicizing the identity of that person (who might be famous)?
- o in general, should sales of sperm be permitted--or only true donations?
- o to what extent should eugenic principles be used in selection of sperm for AID?

No sooner had the states begun to deal even in an incomplete fashion with the issues posed by AID than new techniques came into use for transferring germinal material and creating children with multiple "parents." Ironically, the "solutions" created for AID actually increase the problems in using these other techniques. (For example, the husband of a "surrogate mother" would, in states that have AID laws, have to "nonconsent" to his wife's insemination by the prospective father of the child, in order to keep the child from being legally treated as his own.)

Much more than AID, certain of the new techniques create situations never dreamt of in existing law. The possibility that a woman may bear the child of a man other than her husband is hardly something new; the problem for the law was in fashioning fair and sensible adaptations of the usual rules (about adultery and legitimacy) for a situation in which a husband was collaborating with his wife and her physician in bringing about this result. Yet until egg donation and embryo transfer become clinical realities, it was unheard of for a woman to bear another woman's child. This presents novel questions, such as:

- o may a woman who agrees to carry a child conceived from the egg of another woman, to whom she agrees to give the child at birth, be legally constrained in her personal practices or medical choices during pregnancy?
- o may a woman who gives her egg (before or after fertilization) to another person assert any continuing control over the product of conception, in the laboratory, the clinic, the body of another woman--or even after birth?
- o can the legal status of a child vis a vis its genetic, gestational and social mothers (and fathers) be left to the agreements reached amongst them, or should certain rules be established--so that, for example, a child is always regarded as the child of the woman who bears the child, until properly adopted by someone else?

In addition to the new issues, all the unresolved questions raised by AID--such as the acceptability of sales, of explicit eugenics policies, of a "right" to access to the germinal material for infertile people, of appropriate record-keeping

procedures, and of the reciprocal rights and obligations of the various parties--will need to be resolved for the ovum transfer procedures that are the female equivalent OF AID.

SOME STEPS THAT ARE NEEDED

The new reproductive possibilities can--and should--be seen as a spur to think afresh about parenthood and to develop sensible social policies, rather than as a reason to throw up our hands in resignation over the complexities that they introduce. My own suggestions are that:

1. A multidisciplinary public body be charged with investigating the new reproductive possibilities (among other bioethical issues), providing the framework for a public debate about their social, legal, and ethical implications, and making recommendations to appropriate public and private groups for action.
2. The National Conference of Commissioners of Uniform State Laws empanel a committee to go beyond the Uniform Parentage Act, in conjunction with the body just suggested and drawing upon its recommendations.
3. That the prime objective in any law be to protect the well-being and interests of the children involved, by including:
 - a. a requirement of adequate genetic and other medical screening of all donors of germinal material,
 - b. provision for confidential records to be kept of the identity of all donors, such records to be available for medical reasons only (such as the subsequent, discovery of a genetic disorder in parent or child) and to provide a basis for tabulation and public health studies,
 - c. limitation on the number of offspring from any single donor,

- d. restrictions on the use of frozen germinal material after the death of an identified person from whom the material was derived, not only to avoid the difficulties in settling estates but more important, to avoid intentionally creating "orphans,"
- e. explicit rules about the financial and other obligations of those who use the new techniques, even when the process or results do not turn out as anticipated (e.g., when a handicapped child is born or when a "gestational mother" declines to give up a baby after its birth), all aimed at ensuring each child will have a family to care for it.

4. That the law follow the precedent already set by the prohibitions on "baby selling," and discourage the commercialization of reproductive techniques that occurs when payments are made for eggs, sperm, or embryos.

5. That steps be taken at the state and federal levels to clarify the status of *in vitro* fertilization and other forms of extracorporeal manipulation of germinal material--specifically:

- a. The Secretary of Health and Human Services should act on the May 1979 report of the Ethics Advisory Board (EAB) on IVF research and should appoint a new EAB (pursuant to 45 CFR 46) to review research activities that involve the manipulation of human eggs, sperm and embryos, and
- b. state laws on fetal research should be clarified so that they will not chill research or service activities using human eggs and sperm, provided that such activities are in accord with accepted professional and governmental standards and procedures regarding safety, justified need, etc.

I am sure that others may disagree with some of these proposals, just as they will have other valuable suggestions for the steps that society will need to take to increase the benefits the new reproductive options provide to individuals and to

society, while also minimizing the harm they might cause. What is lacking now is not recognition of the issues but the means to address them in a thoughtful public fashion. This need was recognized by the President's Commission in its final report (see Attachment), and it remains today. I hope that your hearings prove to be a step toward meeting that need.

Summing Up

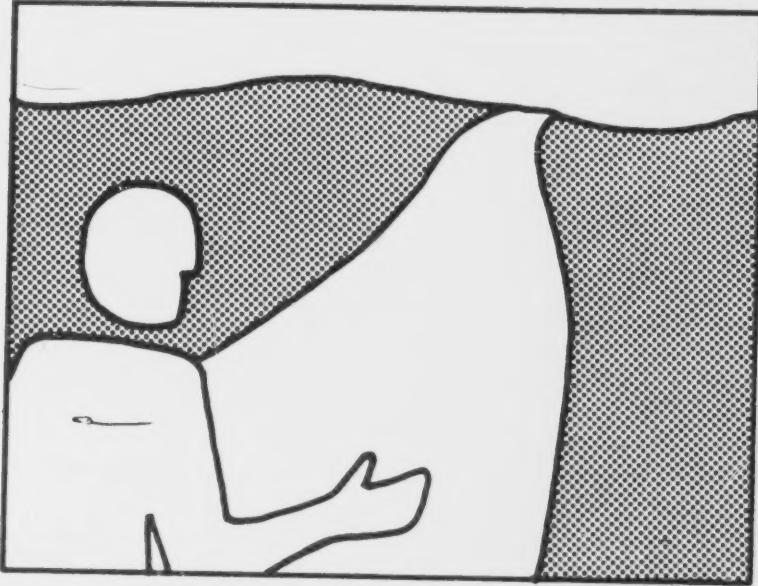
**Final Report on Studies
of the Ethical and Legal
Problems in Medicine
and Biomedical and
Behavioral Research**

March 1983

**President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research**

Summing Up: Chapter 4

resolution today. In a little more than three years of study, however, this Commission has had no thought of either exhausting the range of important concerns that deserve to be addressed or of closing the book on the issues it has studied.



On some of its topics, the Commission has specifically suggested that means be found to continue the process of scrutiny and recommendation. For example, in its Second Biennial Report on the rules governing research with human subjects, the Commission noted the need for one or more oversight bodies, both to aid decisionmakers in resolving ethical issues raised by particularly sensitive research projects (a role briefly fulfilled by the Ethics Advisory Board in DHHS, for example) and to ensure that the Federal rules and their implementation continue to achieve an appropriate balance between advancing science and protecting human subjects. Similarly, the Commission proposed several alternative means through which the ethical and social evaluation of genetic engineering that it has begun can be continued—an evaluation that will be needed as the impact of that rapidly progressing field comes to be more widely felt in society.

If the President and Congress were to decide to constitute another body with a broad mandate in bioethics, the present Commission believes that its agenda ought not to be too fixed, so that it can take on those subjects that are most urgent and significant at the time. There need be no concern that such a body would need to search for issues. For example, medical interventions over the last several decades in human reproduc-

Recurrent Themes

tion have raised a number of issues that have never been fully addressed, much less resolved:

- Artificial insemination, which has been used in human beings for many years, is now involved in tens of thousands of births each year. Yet the chaotic state of the law on this subject, as well as disagreement about the relevant ethical considerations, has led to practices—such as partial or nonexistent record-keeping by many of the physicians involved—that are neither good medicine nor good ethics.
- In the past several years, American physicians have successfully performed human *in vitro* fertilization and embryo implantation, and the number of couples in treatment each year is increasing swiftly. The potential now exists for the chaos surrounding artificial insemination being repeated with egg donors and borrowed wombs. Such developments seem likely in light of what has been described as a "boom in surrogate mothers."¹⁹ In the past several years, a network of women, physicians, and lawyers has developed that can arrange for a "surrogate mother" for couples with female infertility. The shock many people feel at this development may have contributed to society's failure to produce an ethically and legally coherent response that would provide appropriate protection to the interests of all involved, most particularly any children produced.
- Many of the biomedical advances in this area have important implications for children, born and unborn. These implications extend beyond matters of their physical health (for example, increasingly sophisticated and wide-ranging means of antenatal diagnosis of genetic disorders, the repair of an organic defect while a child is still in the womb, and so forth) to the ethical and legal conception of human beings at various points in the process of reproduction, development, and birth.

At the opposite end of the spectrum of life, the attention of patients, physicians, and the guardians of the public purse is focused on efforts to forestall imminent death through intensive medical, surgical, and nursing care. Within the foreseeable

¹⁹ See, e.g., Carol Krucoff, *Focus: The Surrogate Baby Boom*, WASH. POST, Jan. 25, 1983, at C5; Jay Mathews, *Surrogate Motherhood: Becoming an American Growth Industry*, WASH. POST, Jan. 24, 1983, at A2; *When Women Bear Children for Others*, N. Y. TIMES, Dec. 22, 1980, at B6; George F. Will, *Surrogate Mothers*, WASH. POST, Dec. 14, 1980, at C7; *Delivery of Surrogate Mother's Baby Is Reported*, N. Y. TIMES, Dec. 11, 1980, at A25; Theresa M. Mady, *Surrogate Mothers: The Legal Issues*, 7 AM. J. L. & MED. 323 (1982).

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After graduating from Swarthmore College and Yale Law School, where he served as Note and Comment Editor of the Yale Law Journal, Professor Capron clerked for Chief Judge David L. Bazelon of the U.S. Court of Appeals for the District of Columbia Circuit. From December 1979 to March 1983 he served as the Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, a congressionally chartered body that reported on a wide range of subjects in the area of bioethics and public policy. In April 1984, the American College of Physicians presented the Rosenthal Foundation Award to Professor Capron for the contribution to health care made by the work of the President's Commission.

In addition to his responsibilities for the 16 volumes issued by the President's Commission, Professor Capron has written or edited six books (including Law, Science and Medicine and Catastrophic Diseases: Who Decides What?) and more than 70 articles or chapters in professional journals, books and general publications, and serves on numerous editorial boards. He is a Member of the Institute of Medicine (National Academy of Sciences), a Fellow and Board member of the Institute of Society, Ethics and the Life Sciences (The Hastings Center), and a Director of the American Society of Law and Medicine. He also serves on the Board of Managers of Swarthmore College.

Professor Capron appears frequently on television and radio programs (Good Morning America, Today Show, CBS Morning News, ABC Nightline, MacNeil/Lehrer, etc.) and has testified before committees of the Congress and state legislatures on many issues of public policy raised by the life sciences, ranging from genetic engineering and cancer research to organ replacement and the "definition" of death. His principal teaching and research interests are torts, the professions, and the social and legal aspects of medicine and science.

Mr. GORE. Well, thank you very much. I really commend your testimony to those reading this record, it's excellent.

I'd like to withhold questions and go to the remaining members of the panel, beginning with Prof. John Robertson, the Marrs McLean professor of law, University of Texas School of Law in Austin. Welcome, and please proceed.

Mr. ROBERTSON. Well, it's my pleasure to be here, and I welcome this opportunity to discuss these issues.

A number of questions have been raised. I think it might be helpful in trying to answer these questions, if we approach it in terms of the basic conflicts that exist in this area. And I think the basic conflict is between the reproductive liberty of the parents—and I want to focus on married couples—and then look at the kinds of interests that their actions might affect, and the circumstances in which those interests might justify restricting their liberty.

As you know, there's a strong tradition of procreative liberty in the United States, as seen in the notable absence of laws restricting reproduction by married persons. The Supreme Court, since 1965, at least, starting with *Griswold v. Connecticut*, through the birth control *Roe v. Wade* and abortion cases, has given explicit constitutional protection to the notion that at least a married couple has a right of marital privacy in establishing and maintaining a family.

It seems to me that these cases strong—furnish very strong support for the notion that a married couple has a right to engage in noncoital collaborative reproduction, that that is essential for them to realize their reproductive plans.

And what that would mean is that they have a right to make contracts with physicians, or with third parties, with the provision of embryo, sperm, or egg, or even uterus of another, if that is essential for them to meet their reproductive plans. And I think it important to recognize that this right exists.

No one would quarrel with the fact the married couple has a right to produce a child through normal coitus. If they are unable to, because of physical factors, it seems to me that the reasons why we protect the right to reproduce naturally, would also give them the right to use noncoital means within the marital relationship. But if one of them lacks one of the necessary factors, to use the systems of a collaborator, a third-party collaborator as well.

Now, the importance of this, recognition of these choices as a constitutional protected right, is that the State has to come up with a good reason for restricting it. Moral distaste, a sense that it is wrong to reproduce and make families in this way, won't do to restrict a right of this sort.

And since many of the concerns in this area concern moral revulsion, or moral distaste, it seems to me that places a great limit on the ability of the States to interfere in this area.

Well, let's turn and look at some of the interests that have been proposed for limitation of a married couple's procreative rights in this area. Essentially, there's four main interests: Protection of embryos, protection of offspring, protection of reproductive collaborators, and then societal concerns with commercialization.

Let me say a brief word about each.

First of all, the protection of embryos. An embryo is a potential person; it is not yet a person; it may simply be a clump of cells not even differentiated. Yet, it seems to me that it still deserves some protection because of its potentiality to be a human person.

Well, if that's so, a desire to protect embryos does not justify steps—would, at most, justify steps to prevent their destruction, but should not interfere with activities involving the preservation of embryos, embryo adoption, gestational surrogates, or other techniques that are used to take existing embryos and bring them to birth.

The concern with embryos should apply only at the stage where the persons providing the egg and sperm for the embryo now wished to destroy the embryo.

And it seems to me at this point, the State could possibly, if it shows, intervene to prevent a married couple from having an embryo of theirs destroyed. Abortion case, *Roe v. Wade*, would enable them to refuse implantation that embryo in the wife, or it seems to me that *Roe v. Wade* would not give them the option of destroying it as well. But once we separate out the genetic aspect of reproduction from the gestational and rearing, that there is, I think, a lot of room there for States, Federal Government, to intervene to protect embryos if it chooses.

At the very least, even if this distinction I'm suggesting is not recognized, at the very least, the State would have the power to protect embryos in cases of orphan embryos, where the genetic sources are unknown, or their instructions are unclear; in cases of disagreement between gamete providers; or in cases where a person orders destruction of an embryo pursuant to a will.

Let me turn to the next interest then: protection of offspring. Obviously, though procreative liberty is involved here, it is not an absolute right; protection of offspring would be a very important reason for limiting it.

However, when we look at the ways in which these transactions occur, and look to see if future offspring are actually harmed by then, it becomes much more difficult to find the kind of concern with future children that would justify infringing a right of this sort.

I'll skip over the discussion of physical damage, because I think we're assuming that in most cases there will not be physical damage, and turn to the resulting family relationships, which concern a lot of people, the confusion of lineage, as some say, from separating the genetic, gestational and rearing aspects of parentage here.

The problem is that our society has a long tradition of separating genetic, gestational, and social parentage, from adoption, death or divorce and remarriage, through the acceptance of AID. Or if you just think of how we share rearing in our society—we have baby sitters, we have day care centers, we have a whole variety of people who collaborate in reproduction in the rearing process.

Take a one collaborative arrangement that is now possible through the new noncoital technology: embryo adoption. The notion that a couple who have satisfied their reproductive plans, but have preserved some embryos, might want to make that embryo available to another couple.

Again, to think that there's no basis here for infringing such a choice on their part, because it protects the interest of the embryo who will then be brought to term, rather than be destroyed.

Second, the fact that someone other than the genetic parent will be gestating and rearing the child, is really not so different from ordinary adoption and, thus, in terms of protection of the offspring should not be a problem at all.

Indeed, if we look at yet another novel arrangement, it seems to make a lot of people uncomfortable, but when we really examine it, I'm not sure there's much of a—as much of a threat there to the child as some think; there's the question of a gestational surrogate, women who gestate the embryo of another and return it to them after birth for—for rearing.

Now, if we prohibited such gestational contracts, or failed to enforce them when they came up in court, it seems to me that would be a serious infringement of the reproductive rights of the woman involved.

Take the case of a woman, for example, who has had—a hysterectomy, but retained her ovaries. Unless she can recruit another woman to lend, or even rent, her uterus for gestation, she will not be able to beget and rear a child of her genes. To prohibit her from doing so in this case, I don't think can be justified in terms of the well-being of the offspring; again, because assuming that we have a fit parent, this is a pattern that we see in society through adoption and many other techniques.

A third interest that has been proposed for restricting of procreative liberty of married persons other than the interests of the embryo, or the future offspring, is the interest of the reproductive collaborators that they may call upon to assist them to reach their reproductive goals.

The argument is made that with contracts among parties for reproduction should not be honored because it may hurt some of the parties to the contract. Well, that kind of paternalism is not well received in our present scheme of individual liberties, and I'm not sure it should apply here.

The main need for regulation in this area would be to assure that the contracts were knowingly, freely entered into by people who are fully aware of the consequences—and they are important consequences—and, therefore, they should have legal representation, independent counsel for each party.

It seems to me that that's the main focus for—or the main need for regulation to protect reproductive collaborators. And it's a need that is especially important when the contracts are made with physicians, because often physicians will be brokers, or middle persons here, for transfer of gametes and embryos among other parties.

Mr. GORE. Professor Robertson, I'm—we have a vote on the House floor. Congressman Durbin has gone on over and is going to come right back as soon as he votes, so we'll do a little shuttle here. And the recess shouldn't last more than 6 to 8 minutes, so with your indulgence we will recess for that brief period of time.

[Recess.]

Mr. DURBIN [presiding]. If everyone will resume their places we will continue on.

Please forgive this congressional tag team that we have here, but we are called to vote and testify and be in several places at once. It makes it as difficult as trying to answer a docket call in some places.

Professor Robertson, I believe you were testifying.

Mr. ROBERTSON. Yes.

I was discussing the fact that—that our constitutional tradition protects procreative choice by married couples, and that protection would extend to their choice to use noncoital means of reproduction, indeed, noncoital collaborative means of reproduction.

And some of the problems that have been raised with that—I was going through—and at the time that we broke, I was discussing the claim that use of these techniques will hurt the offspring because it will mess up, so to speak, family relationships. It will have a—a bad psychosocial impact on the child. And yet, when we look closely at what is actually going on, the use of collaborative noncoital techniques is really not all that different than occurs now in ordinary adoption or other forms of the family—it seems to me should be evaluated in the same way.

Even something as strange sounding as gestational surrogate, seems to me, on close analysis, bears some scrutiny as—as a way, that if it is necessary for a married couple to reproduce in this way, perhaps should be within their discretion. And an example I cited there was a woman who has had a hysterectomy but retained her ovaries. She would like to have a child through IVF and embryo transfer. It would be possible for an egg to be removed from her surgically, fertilized with her husband's sperm, externally; and then transferred to another woman who gestates it, and then returns it for her to rear.

It is very difficult, it seems to me, to prohibit that on the grounds that it will harm the offspring. Because all we have here is a separation of gestation from the genetic and rearing aspects of parentage—that occurs in adoption. Here, the rearing mother is also the genetic mother, so everything, there'd be a stronger case for allowing that to occur than in the case of ordinary adoption.

And then I was about to address the issue that some people would think that there should be a limit on the contracts that married couples make for noncoital collaborative reproduction in order to protect the reproductive collaborators; to protect women who make contracts to gestate; and then when the time comes to go through with them, to continue the pregnancy rather than abort, or to relinquish the child upon birth don't want to do so.

It seems to me that freedom of contract should be—should be given a great deal of sway here, and even to the point of perhaps enforcing such contracts against such women. I mean, after all, the only way they got an embryo—the only way the woman got an embryo to gestate was because this married couple allowed their embryo to be transferred to her for gestation.

Assuming that both parties are fit parents, it is not at all clear to me that—that the gestator's interest there in retaining custody should take precedence over the married couple's interest in fulfilling their reproductive plans, especially when they provided the embryo in the first place. It may be possible to at least award dam-

ages for such a contract breach, or perhaps even specific performance.

One thing I want to—my final point, which is that a fourth interest that has been put forward here as a cause for concern, as a cause for restriction of these arrangements, is to prevent the commercialization of reproduction. People object, they find it extremely discomforting, the notion that we're buying and selling embryos, or that we would be paying salaries to gestational surrogates.

I think it's important to distinguish the concerns underlying these sentiments, they're important.

I don't think that they can be justified in the same way that baby-selling laws are justified to protect the mother or children from abuse. Gamete or embryo providers, or gestational surrogates, represented by independent counsel in making these arrangements, are not vulnerable to the coercion or exploitation that an unwed mother in an era of stigma was—it's not the same need. Nor is there danger that persons who pay to adopt embryos are unfit parents any greater than the danger of child abuse occurring as to ordinary coital reproduction.

I think the real concern here is the image of buying and selling embryos—buying and selling people. It seems to me that this image that in buying and selling embryos, like selling cattle, or slaves, is really misleading rhetoric. We have to think more carefully about it.

Purchase of an embryo for adoption is purchase of a limited bundle of rights regarding the embryo and resulting child. The seller is clearly giving up the right to gestate and then rear that child. And the purchaser is buying the right to gestate and rear. But purchase of that embryo does not give rights to destroy, or abuse, or manipulate the embryo and resulting child that would not otherwise exist. It's not the right to treat the resulting child as a commodity subject to any wishes of the person as is the case, say, with cattle, putting animal protection laws aside, or a car.

It seems to me when people talk about ownership or property here, that is troubling, because they think that if you are the owner of the property you can do anything you want with it. And, of course, that does not follow with purchase of embryos or paying surrogates money to carry. Child abuse and neglect laws would still apply with criminal and civil sanctions available for—for mistreatment.

It seems to me the main concern here with—with paying money for embryos or salaries to gestators is the affront to moral sensibility—their rises from paying for such an intimate, traditionally non-commercial function.

Now, in our society, blood and sperm are sold; minors, professional athletes, petrochemical workers, and a whole host of others sell part of their life in health and vitality, and it is accepted.

Yet, some people think it dehumanizing in a special way to traffic in embryos or pay rent for uterine services, in much the same way they think the payment of money for sex or body organs to be wrong.

My point is that those judgments, those moral judgments, are perfectly legitimate for people to make. However, it's not clear to me that the State has the power to make those judgments, if

making them will stop married persons from reproducing in the only way possible.

If you prevent the sale of embryos and the payment of salaries to surrogates in all cases, you may interfere significantly with reproductive plans, because money may often be essential to recruit parties with the qualifications necessary for the planned reproduction to occur.

If a ban on paying money interferes with reproductive freedom, then a justification beyond moral or aesthetic revulsion is necessary to uphold such a law.

When the interest of the parties or offspring are seriously affected, then, of course, you should step in and regulate the transaction. But if it's merely to implement a certain sense of moral revulsion, it seems to me that that is not adequate to override the exercise of constitutional rights to procreate of married persons.

Thus, to conclude, as these techniques become more available, more diffused through society, and more used, we have to recall that their use falls squarely within constitutionally protected traditions of procreative liberty.

The States' interest in protecting embryos, offspring, and reproductive collaborators, and preventing commercialization, is insufficient in most cases, I believe, to prohibit use of these techniques in all cases. Regulation in a few areas, however, is permissible when we examine them and see how the conflicts work—work themselves out, especially regulation designed to make sure that the parties act freely and knowingly when they acquire or relinquish rights to gametes or embryos.

In the final analysis, the reservations expressed in these hearings, and I think have led to them, are rooted in a deep, perhaps almost religious sense, that manipulation of embryos is wrong because of the unnatural crossing of boundaries that it entails.

These considerations deserve respect at the personal moral level. However, I do not believe they are valid grounds for public policy.

I appreciate the opportunity to present these views.

[The prepared statement of Mr. Robertson follows:]

U.S. House of Representatives
Committee on Science and Technology
Subcommittee on Investigations and Oversight
August 8, 1984

Prepared Statement
John A. Robertson
Professor of Law
The University of Texas at Austin

Mr. Chairman and members of the Subcommittee: I welcome the opportunity to discuss with you the legal and ethical implications of Human Embryo Transfer.

Human embryo transfer is an important development for two reasons: (1) it provides the power to separate and recombine among several persons the genetic, gestational and rearing aspects of reproduction, and (2) it provides the ability to suspend and then restart the process of reproduction after conception has occurred.

As infertility increases, we can expect more couples to turn to human embryo transfer and other forms of noncoital reproduction to satisfy their procreative plans.

The possibility of creating, freezing, manipulating, and transferring embryos among different persons has aroused both wonder and fear, and raised the question of the need for regulation. I would like to address the question of regulation by looking at two issues: (1) the extent to which procreative freedom is at stake; (2) the extent to which the interests of embryos, offspring, reproductive collaborators or society would

justify regulation.

I. Procreative Liberty

Any consideration of the need for regulation of embryo transfer must begin with the recognition that use of such techniques involves the exercise of reproductive freedom. Embryo transfer was developed to relieve the suffering of infertile married persons and will be used primarily to fulfill the reproductive plans of married persons.

There is a strong tradition of procreative liberty in the United States, as seen in the notable absence of laws regulating reproduction by married persons, and more recently in Supreme Court decisions. Starting with Griswold v. Connecticut in 1965 and continuing through Roe v. Wade and later abortion cases, the Supreme Court has explicitly recognized as a fundamental constitutional right choices about the establishment and maintenance of a family. These cases furnish strong support for extending to married couples the freedom to reproduce through noncoital collaborative techniques, including external conception and embryo transfer.

The argument for a right to reproduce noncoitally--for a right to embryo transfer and to make contracts with third party collaborators for gametes, embryos and gestation--is

straightforward.¹ The Griswold-Roe v. Wade line of cases clearly establishes the right of single and married persons to avoid reproduction through the use of contraceptives and abortion, and the right, if a child has been born, to control the rearing process. Decisions to reproduce comprise personal interests equal in nature and import to the interests in not reproducing. We thus discern behind the right not to reproduce a larger principle of marital autonomy in procreation, which includes a broad freedom for married couples (and possibly for single persons as well) over decisions to reproduce.

The principle underlying these holdings includes the right of a married couple to have children coitally. If so, it is difficult to see how noncoital, collaborative reproduction by married persons can be treated differently. If married persons have a right to have and raise children, it should follow that they have the right to enlist the support of physicians and others to obtain reproductive factors (sperm, egg or uterus) that will enable them to do so.

The constitutional status of noncoital reproduction significantly limits the state's power to regulate. Protection as a fundamental right means that the state may regulate only to serve compelling state interests that cannot be protected by

¹ For a more complete analysis of this right, see J. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy and Childbirth*, 69 Va. L. Rev. 405, 407-433 (1983).

other means. Moral scruples alone, though adequate to support most kinds of state regulation, are inadequate to support limitations on fundamental rights.

II. Justifiable Regulation of Noncoital Techniques

When we examine the concerns raised about noncoital reproduction we see that few, if any of them, justify restricting operations with embryos that are necessary for married couples to procreate.

1. Protection of Embryos

Some people are concerned about embryo transfer because they think that embryos are moral entities in their own right, or because they think that as potential persons embryos deserve respect. They are against IVF and embryo transfer because it will inevitably lead to destruction or damage to embryos, and thus show disrespect for human life.

A desire to protect embryos may justify steps to prevent their destruction, but should not stop activities such as embryo freezing, adoption, and gestational surrogates that could lead to embryos being implanted in a uterus and brought to birth. If such maneuvers damage the resulting children, the harm is to those future children and not to the embryo.

The main conflict between procreative liberty and embryos

concerns whether the genetic source can order destruction of an embryo formed from his or her gametes. Note that the freedom asserted here is the freedom to prevent reproduction by transmittal of one's genes, and not the right to reproduce noncoitally. Whether the state could require that all embryos be implanted or preserved for implantation in a willing recipient (adopter) depends on the scope of the right not to procreate recognized in the contraceptive and abortion cases.

It is possible that the Supreme Court, consistent with Griswold and Roe v. Wade, would allow the state to require adoption of unwanted embryos. The right not to procreate protects a person's interest in avoiding the burdens of gestation and rearing (or relinquishment) that along with gene transfer occur in reproduction. When the physical and social burdens are missing, what reason is there to want to avoid gene transfer? If neither gestation nor rearing will occur, then a person's interest in avoiding gene transfer may not deserve constitutional protection.

We can only speculate as to how the Supreme Court would treat the matter, for the Court has not separately analyzed the different interests that persons have in avoiding reproduction. The powerful social and personal connotations traditionally aroused by the genetic link may stem from the rearing and gestation that usually accompany genetic reproduction. When the interest in gene transfer is separated

from the gestational and rearing aspects of reproduction, which IVF and embryo adoption permit to occur, the Supreme Court could find the genetic link alone insufficient for constitutional protection. The Court, for example, has held that blood-tie alone will not give an illegitimate father the right to rear or prevent the adoption of his son, if he has not previously taken a rearing role. If strict anonymity is maintained and no unwanted contact or rearing imposed, the Supreme Court could consistently with Roe v. Wade uphold state statutes requiring that all unwanted embryos be preserved and made available for adoption.

At the very least the Supreme Court could reach such a result in the case where the genetic sources are unknown, in the case of disagreement between the gamete providers over destruction (since there is no unwanted gestation, there is no conflict with the cases invalidating spousal consent requirements for abortion) or when a person orders destruction in a will.

2. Protection of Offspring

A justification for regulation would be protection of the resulting children. Children born of noncoital reproduction could be hurt because of the (1) physical manipulation involved in external conception, transfer, freezing and thawing, or (2) the resulting relationship to reproductive collaborators.

a. Physical Damage

IVF and embryo transfer is now considered a safe and established therapy for oviduct blockage. As more evidence is gathered and new techniques tried, it is possible that children born of external conception, embryo transfer, freezing and thawing will turn out to have a higher rate of congenital deformity than occurs in coital reproduction. Ethicists such as Ramsey, Tiefel, Walters and Kass have argued that it would be unethical to allow noncoital reproduction where the birth of damaged offspring is likely.

Such a view, I think, is ethically and legally misguided because it overlooks the crucial fact that without IVF and embryo transfer, the damaged child would never be born. There is no way for this person to be born other than by the very means--IVF--that creates the risk of damage. The damage is avoidable only if the child's birth is avoided. Thus banning IVF to benefit the child will deprive the child of the chance to exist at all. Only in extreme cases amounting to wrongful life would this fear justify prohibition of embryo transfer.

This case is to be distinguished from that in which the child (whether born of coital or noncoital conception) could have been born healthy, if the parents or doctor, had taken reasonable measures to avoid harm. Where the harm is avoidable and the child can be born, regulation to prevent the unhealthy birth is desirable and justified.

The state may be justified in discouraging the use of IVF if handicapped children were born at a higher rate than in coital reproduction only to prevent rearing and cost burdens on others, not to protect the offspring. However if the procreators will rear the offspring themselves, those burdens would not arise and a legitimate ground for restricting their right to procreate would be missing.

Nor should freezing embryos for later use by the couple be banned because of a threat of damage to future offspring. The technical capacity to freeze, thaw and successfully implant human embryos presents a new array of options for infertile couples seeking to reproduce. Now that cryopreservation is possible, not all embryos need to be transferred to a uterus shortly after fertilization. Through freezing and thawing of embryos, a woman can seek a subsequent pregnancy without having to undergo the rigors of laparoscopy under general anesthesia.

Laws prohibiting embryo freezing to protect offspring would substantially impair a woman's ability to reproduce. She would be forced to undergo another laparoscopy, if the first transfer failed, or if she wanted later children. Moreover, implanting all embryos immediately after fertilization, though increasing the chance that at least one embryo will implant, could reduce the chance of any single one implanting. Preventing harm to offspring from freezing would not provide sufficient justification to ban freezing. Once again, the very act

creating the risk of damage is the act that enables these persons to be born.

b. Psychosocial Damage From New Family Relations

Concern has also been expressed that IVF and embryo transfer, though physically safe, will lead to embryo adoption, gestational surrogates, ovum donation and other third party combinations that will alter parent-child relations to the ultimate detriment of the child.

IVF and embryo transfer, by introducing a third-party provider of gametes or gestation, do allow collaborative reproduction to occur on a greater scale than it has. But there is nothing novel about other persons collaborating in reproduction.

(1) Embryo Adoption

The separation of the rearing from the genetic parent is prevalent in our society through adoption, death or divorce and remarriage. Embryo adoption provides the novel twist that the non-genetic mother also gestates, rather than merely rears, as

occurs in ordinary adoption. This difference, however, does not appear to have moral significance. It may actually make embryo adoption more desirable, for the mother who rears has also gestated, and thus is likely to be even more strongly bonded to the child.

Protecting future offspring is not a sufficient basis for prohibiting such transactions, though it may be a basis for regulation. In most cases, the offspring are benefitted, for there is no other way for them to be born. Privately-arranged embryo adoptions thus should be permitted, at least to the extent that independent postnatal adoptions are. Physicians, lawyers and others who broker these arrangements could be licensed and subject to regulation to discourage harmful practices. The right of children to know their genetic parents may also be protected.

(2) Gestational Surrogates

Embryo transfer also raises the possibility of gestational surrogates--women who gestate the embryo of another and return it to them after birth for rearing. Prohibition of gestational surrogates or failure to enforce contracts with surrogates would be a serious infringement of reproductive rights, for example, of a woman who has had a hysterectomy but retained her ovaries. Unless she can recruit another woman to loan her uterus for gestation, she will not be able to beget and rear a

child of her genes.

The well-being of future offspring does not justify a ban on gestational surrogates. Since transfer of an embryo to the uterus of a woman not providing the ovum is possible without physical damage to the resulting child, the feared harm resides in the child being reared by a person who has not gestated him. While it may be desirable to combine rearing and gestation in the same person, the lack of gestational bonding with the rearing parent is hardly a serious harm to the child. In ordinary adoption women rear children whom they have not gestated without apparent harm and often with great benefit, and women who gestate do not rear. Noncoital separation of rearing and gestation should also be acceptable. Indeed, it may be even more desirable for the child than ordinary adoption, since the rearer will also be the genetic parent.

3. Protection of Reproductive Collaborators

In addition to effects on the resulting children, embryo transfer and other noncoital collaborative techniques can affect the reproductive collaborators--the persons providing the genetic, gestational or rearing aspects of reproduction. But these effects do not justify nonenforcement of the collaborators' agreement for allocating rights and duties to each other and the resulting child.

The parties themselves are the best source for determining

what will serve their reproductive interests. Since their decision may have significant social, psychological and economic ramifications throughout their lives, such contracts should not be entered lightly. However, the risks to the contracting parties do not justify paternalistic interference with their choices.

The main focus of regulation to protect the parties should be rules designed to assure informed consent and to prevent fraud and coercion in making reproductive contracts. Rules specifying the provisions to be covered in the contract, disclosure of specific consequences, waiting periods, and requirements for legal representation provide a structure to assure the autonomous exercise of procreative choice. Such rules are thus both desirable and constitutionally permissible.

Ground rules for contract formation to protect the free choice of the parties are especially important when a physician is providing or obtaining gametes and embryos or brokering agreements for them. In many cases the doctor, as broker or middleman, will be the source of gametes or embryos for reproductive use by others. He will play a powerful or even dominant role in the parties' transfer of control over sperm, ova and embryos. As a "repeat-player" with greater knowledge than the "one-time players" who come to him, he may have a great advantage in negotiating the transfer of reproductive rights. Ground rules designed to assure free, informed

contract formation among reproductive collaborators, such as waiting periods and legal representation, are therefore in order, as would be regulation that assures that the physician will carry out his agreement.

The right of reproductive collaborators to make contracts is well-recognized when male gametes are transferred. The sperm source usually agrees to relinquish all rights and duties in the offspring and the consenting couple take them on. A few cases have gone farther and recognized the sperm source's right to retain visitation and support obligations in the offspring when the recipient agreed to that arrangement. There is no reason why the provision of ovum, either directly or in the form of an embryo, should not also be controlled by the agreement of the parties.

The strongest case for overriding the contract of the parties arises when a couple seeks to enforce a gestational surrogate's agreement to relinquish the child resulting from their embryo. Many people think that the gestational bond is so strong and intimate that the woman undertaking gestation should always have final say about abortion or custody.

However, the gestational surrogate contract was freely entered into and was relied on by the couple providing the embryo to fulfill their reproductive plans. Assuming all parties are fit parents, it is not clear why the gestator's desire to rear should take over a similar desire in the genetic

source. The surrogate never would have had the embryo to gestate and birth if she had not agreed to return it nine months later. Failing to enforce such contracts, by damages if not by specific performance, will cut off an option essential for people to fulfill their reproductive plans.

4. Prevent Commercialization

Many people object to buying and selling embryos or paying salaries to gestational surrogates, and urge regulation to prevent commercialization of reproduction.

It is important to distinguish the concerns underlying these sentiments. In most instances they cannot be justified as baby-selling laws are to protect mothers or children from abuse. Gamete or embryo providers or gestational surrogates represented by independent counsel are not as vulnerable to coercion or exploitation as was the unwed mother in an era of stigma. Nor is the danger that persons who pay to adopt embryos are unfit parents greater than the danger of child abuse occurring after coital reproduction.

The image of buying and selling embryos like cattle or slaves is misleading rhetoric. Purchase of an embryo is purchase of a limited bundle of rights regarding the embryo and resulting child. The seller is giving up the right to gestate and rear, and the purchaser is buying the right to gestate and rear. Purchase of an embryo does not give rights to destroy or

manipulate the embryo that would not otherwise exist, nor the right to treat the resulting fetus or child as a commodity, subject to any wishes, as is the case with cattle or other property. Abortion, child abuse and neglect laws still apply, with criminal and civil sanctions available for mistreatment.

The main concern with paying money for embryos or gestation is the affront to moral sensibility that arises from paying for such an intimate traditionally noncommercial function. Even though blood and sperm are sold, and miners, professional athletes, and petrochemical workers sell some of their health and vitality, some persons think it dehumanizing to traffic in embryos or pay rent for uterine services, in much the same way that they find the payment of money for sex or body organs to be wrong.

However, the state's power to block market exchanges that interfere with the exercise of a fundamental right is limited. Preventing the sale of embryos and the payment of salaries to surrogates may interfere significantly with reproductive plans, because money often is essential to recruit parties with the qualifications necessary for the planned reproduction to occur. If a ban on paying money interferes with reproductive freedom, then a justification beyond moral or aesthetic revulsion is necessary to uphold such a law. When the interests of the parties or offspring are not seriously affected, the state may not constitutionally ban or refuse to

enforce contracts involving payments for embryo transfer or gestation, merely because of an affront to moral sensibilities.

Conclusion

Embryo transfer and other noncoital reproductive techniques are now technically feasible and will be used increasingly by persons unable to fulfill their reproductive needs in traditional ways. Such use falls squarely within the constitutionally protected tradition of procreative liberty of married couples.

The state's interest in protecting embryos, offspring and reproductive collaborators and in preventing commercialization is insufficient to restrict use of these techniques in most cases. Regulation in a few areas, however, is permissible, especially regulation to make sure that parties act freely and knowingly when they acquire or relinquish rights to gametes or embryos.

In the final analysis reservations about human embryo transfer are rooted in a deep, almost religious sense that manipulation of embryos is wrong because of the unnatural crossing of boundaries that it entails. These concerns deserve consideration at the personal, moral level. They are not valid as grounds for public policy.

John A. Robertson is the Marrs MacLean Professor of Law at the University of Texas Law School, Austin, Texas, where he teaches Criminal Law, Constitutional law, and Law and Medicine. A graduate of Dartmouth College and Harvard law School (1968), he has written extensively on medical-legal and bioethical issues, and is author of The Rights of the Critically Ill (1983). He has also been a professor at the University of Wisconsin Law School, and in the Program in Medical Ethics of the University of Wisconsin Medical School, Madison, Wisconsin.

Mr. DURBIN. Thank you, Professor Robertson.

Our next witness on the panel is Ms. Lori Andrews, research attorney with the American Bar Foundation in Chicago, IL; also the author of a book, "You Can Have a Baby: New Conceptions," which we'll be glad to plug here today, and happy now to have you testify.

Ms. ANDREWS. An unexpected benefit.

Well, one need only look at Alex Capron's massive chart to realize that medical developments have altered the possibilities for parenting. And as more actors have gotten involved in the drama of reproduction, the law is increasingly being called in to sort out the rights and the responsibilities of the people involved.

What I'd like to do today is to discuss briefly some of the existing laws that appear to cover alternative reproduction and then raise policy questions that must be answered in order to develop adequate regulation in this area in the years to come.

In some States there are statutory barriers to the use of alternative reproduction. Laws adopted for other purposes are broad enough in their language that they could be used to prohibit or restrict alternative reproduction.

The laws of 25 States, for example, prohibit fetal experimentation. In at least six of these States, the language of the fetal research laws is broad enough to ban embryo freezing. Likewise, in 17 States, the fetal research laws constrain embryo transfer after the lavage method.

Other laws create barriers not to a particular form of alternative reproduction per se, but only to its commercialization.

Ten State statutes, which prohibit women from selling a fetus for experimentation, use language broad enough to potentially forbid payment to a woman who undergoes in vivo fertilization followed by embryo transfer.

The most widespread current restriction on an alternative reproduction method covers commercial surrogate motherhood. In that situation the sperm of the husband of an infertile woman is used to inseminate a surrogate mother who, for a fee, will carry the child for 9 months and then release the infant for adoption, by the couple.

Yet, at least 24 States prohibit a mother from accepting a fee in connection with turning over a child for adoption, and at least one court has held that this ban on payment applies to surrogate motherhood as well.

As John Robertson implied, the barriers to the new means of procreation will undoubtedly be challenged in the coming years as violating a couple's right to procreate.

Already, a pending case in California challenges the law that states that the sperm donor is not the legal parent of the child. In that case, a man wants to use surrogate motherhood and be a sperm donor and still be considered the legal mother—legal father of the child, excuse me.

If the constitutional right to privacy to make procreative decisions is found to encompass the right to bear children using alternative reproduction, a law banning these techniques will be valid only if it furthers the compelling State interest in the most narrow way possible.

In the next few years we will probably see increasingly detailed legislation being introduced on the State level to regulate these procedures; rather than the current black and white legal framework of banning or allowing the techniques, State laws will probably be developed to allow their use with recognition of certain compelling State interests in protecting the participants and society.

These laws should be developed in ways that protect the psychological, physical, and financial well-being of the participants in alternative reproduction, including the resulting children.

Close regulation of this area may be more appropriate than in other areas of medicine since the whole purpose is to create an individual if that individual cannot consent to the procedure taking place.

There are other reasons why this field is unique in a regulatory sense. Some of the constraints that act to assure quality in other areas of medicine, of high technology medicine, such as capital or manpower constraints, or the potential for expensive malpractice verdicts, do not operate as forcefully with respect to the new reproductive technologies.

The Warnock Committee suggested that licensing was the approach to take. It seems unlikely that licensing will be a tactic taken by lawmakers in the United States. More likely, specific regulations will be developed that attempt to combat a particular type of harm, such as psychological or physical harm.

Like John Robertson, I'd like to look closely at some of the potential harms that the new means of conception are said to entail.

The new reproductive technologies have emotional ramifications for the couples, the donors, and the children born through these techniques. The use of a sperm donor or surrogate replaces the biological input of one of the spouses in the couple. That individual may feel left out or suffer psychologically as a result.

The donor of a gamete, or a woman who provides a womb for gestation, may also be psychologically disturbed by participation in the process. Some surrogate mothers go through a period of grieving and depression after surrendering the infant.

Likewise, some sperm donors later feel remorse about the fact that they have created children who they never see.

Individuals who are not direct participants in the process may also be affected. The parents of sperm donors in some instances have felt disturbed that their sons have given away their grandchildren.

The existing children of an egg donor sperm donor, or surrogate, might feel fear of abandonment.

An Ethics Committee of the Royal College of Obstetricians and Gynecologists in England recommended against the use of surrogates on the grounds that these women cannot predict beforehand what their attitudes toward the children will be, and that relinquishment might cause emotional stress. The Warnock Committee also opposed surrogacy.

But a policy of banning a particular alternative reproduction based on scanty psychological evidence is inappropriate and also probably unconstitutional. Sound empirical data needs to be col-

lected on the psychological ramifications of participants in the new reproductive technologies before regulations can be drafted.

The psychological effects of the new technologies on the resulting children also needs to be explored. Some who were conceived through artificial insemination and are now in their twenties and thirties feel that they have suffered emotionally as a result of being created through these means. Like adoptees, some artificial insemination children feel they need to learn about their biological fathers, the sperm donors. In the future, embryo transfer babies may have the same questions about their genetic mothers.

Proposed legislation here and abroad attempts to take the psychological ramifications of the new conceptions into account. Proposed Michigan law requires that before alternative reproduction takes place, a marriage counselor, psychologist or psychiatrist counsel the societal parents who will raise the child on the consequences and responsibilities of parenthood, and counsel the gamete donor or surrogate about the psychological consequences of his or her consent.

While these various legislative proposals suggest counseling for the adults involved in alternative reproduction, they approach the psychological needs of the child in a different way. First, they attempt to assure that the child will not be a pawn in a paternity battle.

The proposed Michigan legislation, for example, lets the intent of the couples and the other participants, before the conception takes place, govern who will have the parental rights to the child. So if a surrogate agrees in advance that she will give up the child, she cannot later on try to make a claim to the child.

The proposed Washington, DC, ordinance and the proposed Michigan law would also allow the new conceptions children, when they reach age 18, to learn the genetic and medical history of the donor. The proposed Michigan law would go one step further and release the name of the donor or surrogate as well.

The physical health of the parties to the new reproductive technologies needs to be considered, too. Some women have undergone artificial insemination in order to obtain a child, and have ended up instead with venereal disease or a child with a genetic defect passed on by the sperm donor.

Only in the State of Oregon and New York City are there legal regulations that specify a man with a genetic disease, or a man with a genetic—or a venereal disease, cannot be a sperm donor. The proposed legislation, though, in Michigan and District of Columbia would require screening of donors much as the type that Professor Capron suggested.

Now, does—does the process of the new reproductive technology cause harm to the child in itself? It seems unlikely with in vitro fertilization. The worldwide experience to date has found a lesser number of abnormalities in the children than in the children of natural procreation. But there's some speculation that freezing over a long time period might cause harm to the child through some sort of mutagenic effect of the background radiation.

The new conceptions raise the need for forward-looking laws that determine the paternity of the resulting children; that set forth the rights and responsibilities of the participants in the process; that

provide guidelines regarding the safe undertaking of the procedures; and that make provision for the care of extracorporeal embryos.

The setting of policy in this area, though, needs to be informed by empirical studies of medical, psychological, and financial effects of the techniques on the participants, on the resulting children in nonsociety. To that end, a registry or clearinghouse of information should be established.

Also, as was suggested in 1979 by the Ethics Advisory Board of the Department of Health, Education, and Welfare, a model law should be drafted.

In addition, an ongoing commission has—has been referred to several times in the testimony today, should be established to evaluate existing information on the technologies, with special attention to the effects on society.

The Commission on the New Reproductive Technologies could be a means to assure that the immediate goal of creating a child for a couple who desperately wants one does not overshadow an assessment of the overall risks and benefits of the new conceptions.

Thank you.

[The prepared statement of Ms. Andrews follows:]

REGULATION OF ALTERNATIVE REPRODUCTION —
LOOKING BACKWARD AND LOOKING AHEAD

by

Lori B. Andrews, J.D.

The year 1984 has brought with it medical developments that have altered the possibilities for parenting. The arrival of the first embryo transfer baby showed that it is feasible for a child to have five parents: a sperm donor, an ovum donor, the woman who gestates the child, and the couple who raise it. The birth of a child who had spent two months after conception as a frozen embryo presages the possibility that the normal nine month period between fertilization and birth could be expanded by months, years, or even decades.

The new medical technologies affecting reproduction are raising new challenges for the law. Does a frozen embryo have a right to be born? Can a surrogate mother change her mind and retain the custody of the child she has contracted to bear? Does a wife have a right to be inseminated with sperm of her deceased husband that he froze before his death? Does a child born through artificial insemination have a right to information about the sperm donor? All of these questions, which just a few years ago would have been law professors' hypotheticals, are now actual controversies for which people are demanding answers.¹

In 1979, the Ethics Advisory Board of the Department of Health, Education, and Welfare, in making recommendations on human *in vitro* fertilization and embryo transfer, concluded that the ambiguity regarding the legal status of the children born from the new reproductive technologies and the legal responsibilities of those who permit the use of these procedures warranted the development of a model law.² In the five years since then, the ambiguities which prompted the Ethics Advisory Board's concern and

recommendation have not been resolved, yet the new conceptions are becoming increasingly sophisticated and more widely used. The problem suggests a critical distinction between the medical profession and the legal one: medicine looks forward, while the law gazes backward.³

The medical technologies of surrogate motherhood, embryo freezing and the donation of sperm, ova and embryos are being forced into the Procrustean bed of existing laws on paternity, fetal research and adoption. The result is an insufficient protection of the participants in the new conceptions, including the children. Consideration needs to be given to new legal mechanisms to govern such issues as who controls germinal material once it leaves an individual's body, how legal paternity to the new conceptions child should be determined, what standards should govern the performance of new reproduction technologies, and how the effects of these techniques on the participants and on society can best be monitored.

An analysis of existing laws that could be interpreted to cover alternative reproduction demonstrates the continuing wisdom of the Ethics Advisory Board's recommendation that new laws be drafted to cover these activities. In some instances, the existing laws are ambiguous and do not provide sufficient guidelines to the participants. In other instances, the laws create barriers that might violate infertile couples' constitutional right to privacy to make procreative decisions.⁴ Or there may simply be no laws that address certain critical issues.

States Laws Presenting Barriers To The New Conceptions

In some states, there are statutory barriers to use of alternative reproduction techniques. Laws adopted for other purposes before the new reproduction technologies came into use may be drafted broadly enough to prohibit or restrict them. Of greatest relevance to the techniques of embryo transfer after in vivo fertilization and embryo freezing are the state fetal experimentation laws.

Since these techniques (as opposed to in vitro fertilization) are at the early

stages of development with few successful applications to date, their application in a clinical setting is likely to be considered experimental, and thus could fall under the laws of 25 states that restrict fetal experimentation.⁵ Many of these laws specifically cover research as early as the embryo stage, prohibiting such research except to protect the life and health of the embryo.⁶ In at least six states, the fetal research provisions could be interpreted to ban embryo freezing.⁷ In seventeen states, the fetal research laws would appear to cover embryo transfer after in vivo fertilization.⁸ Some state statutes additionally penalize the woman who donates an embryo to another woman. Seven state statutes, in language broad enough to cover embryo transfer, prohibit women from giving away or permitting someone to use their embryos in an experimental manner.⁹ Five of those state statutes could be used to prohibit a woman from having one of her embryos frozen after in vitro fertilization for use by a second woman.¹⁰

Other laws create barriers not to a particular form of alternative reproduction per se, but only to its commercialization. Ten state statutes which prohibit a woman from selling a fetus for experimentation use language broad enough to potentially forbid payment to a woman who undergoes in vivo fertilization followed by embryo transfer.¹¹

The most widespread restriction on an alternative reproduction method covers commercial surrogate motherhood. In that situation, the sperm from the husband of an infertile woman is used to inseminate a surrogate mother who, for a fee, will carry the child for nine months and then release the infant for adoption by the couple. Yet at least 24 states prohibit a mother from accepting, in connection with releasing her child for adoption, any payment beyond certain statutorily enumerated medical expenses.¹² The Michigan Court of Appeals in 1981 held that this ban on payment applies to the surrogate mother situation as well.¹³ In contrast, a Kentucky trial court in 1983 held that the surrogate arrangement did not fall within the public policy prohibition on the sale of babies since a natural father could not be characterized as either adopting or buying his own child, with whom he already had a legal and natural

relationship.¹⁴

In addition to the laws passed for other purposes which by their language appear to cover infertility treatments involving new reproductive technologies, there are new state laws adopted or proposed specifically to cover alternative reproduction. Bills banning surrogate motherhood have been introduced in three states (Alabama, Michigan and New Jersey) in recent years; at least a dozen jurisdictions have entertained legislation to allow surrogate motherhood.¹⁵ A law enacted in Illinois in 1979 restricts in vitro fertilization by providing that a person who fertilizes a woman's egg outside her body "shall, with regard to the human being thereby produced, be deemed to have the care and custody of a child" for purposes of an 1877 child abuse act.¹⁶ The latter act, in turn, made it "unlawful for any person having the care or custody of any child, wilfully to cause or permit the life of such child to be endangered, or the health of such child to be injured, or wilfully cause or permit such child to be placed in such a situation that its life or health may be endangered."¹⁷

The law thus gave rise to the possibility that an Illinois physician attempting in vitro fertilization might have widespread liability in every action he or she undertook or permitted anyone else to undertake with respect to the embryo. Consequently, physicians were reluctant to offer in vitro fertilization in Illinois.

A legal challenge to the Illinois law, Smith v. Fahner,¹⁸ prompted an opinion by the Illinois Attorney General and the State's Attorney of Cook County that the physician would violate the law only if he or she wilfully endangered or injured the conceptus in the preimplantation stage such as by abuse, mutilation, extermination or harmful experimentation. The physician's decision not to reimplant, if done with the mother's permission, would be permissible as a lawful pregnancy termination (akin to a woman's decision to abort a fetus during the first two trimesters). Although this opinion allowed in vitro fertilization to go forward in Illinois, it is unclear whether transfer of the embryo to a second woman or embryo freezing may be undertaken in conjunction with an

in vitro fertilization program. If an embryo fails to develop further after transfer or thawing, will the physician be criminally liable for having engaged in "harmful experimentation"?

The barriers to the new means of procreation will undoubtedly be challenged in the coming years as violating the couple's right to procreate. If the constitutional right to privacy to make procreative decisions is found to encompass a right to bear children using alternative reproduction, a law banning a reproductive technology will be valid only if it furthers a compelling state purpose in the most narrow manner possible.¹⁹ In the next few years, we will probably see increasingly detailed legislation being introduced on the state level to regulate the procedures. Rather than the current black and white legal approaches of banning or allowing these procedures, state laws will probably be developed to allow their use with recognition of certain compelling state interests in protecting the participants and society.

Control Over Genetic Materials

One issue that will need to be determined under the new laws is the extent to which people will have control over germinal material once it is removed from their bodies. This issue was central in a French dispute in which a woman wanted access to sperm that her husband had frozen before his death.²⁰ A lawyer for the sperm bank maintained that the sperm was an indivisible part of the person, not subject to inheritance.²¹ In contrast, in the United States, sperm banks have allowed women to conceive a child with the sperm of their deceased husbands, so long as the husband provided permission in his will.

The issue of individuals' rights to their germinal material also arose in a case, Del Zio v. Manhattan's Columbia Presbyterian Medical Center,²² where in vitro fertilization was attempted, but a physician destroyed the contents of the petri dish.

There has been a reluctance on the part of courts to view germinal material as the "property" of the donor. The Del Zio case held that the couple had no cause of

action against the physician for destruction of property.²³ Yet sperm, ova, and embryos with their genetic information and ability to produce new life are clearly distinguishable from blood, organs, or other substances removed from the body. The law should recognize an individual's right to control the use of his or her germinal material. Physicians should not be allowed to collect germinal material for one purpose and use it for another without the donor's consent. For example, when a physician collects ova or embryos from a woman during a hysterectomy or sperm from a man providing a sample for analysis, the individual's permission should be required before the ova, sperm, or embryos are used for research or treatment of an infertile couple.

When individuals have their gametes or embryos frozen, they should determine in advance, preferably in writing, the uses to which the gametes or embryos can be put. The conflicts that occur when that is not done were demonstrated by the recent case of the two orphan embryos in Australia whose future is uncertain due to the deaths of the woman who conceived them and her husband.²⁴ Without advance directives, it is hard to determine who should decide about the embryos' future.²⁵ There is virtually no existing law in the United States that would cover the situation, with the exception perhaps of the Illinois *in vitro* law which, by giving the physician custody of the embryos, might give him or her the right to decide about their future.

Both the American Fertility Society²⁶ and the Australian Medical Research Council²⁷ have issued guidelines which stress the need for the consent of donors before their genetic material can be used. The American Fertility Society additionally specifies that donors can authorize cryopreservation of embryos either for use within the reproductive life of the donor or for donation to another infertile couple.

A proposed Michigan law provides that before embryos are frozen, the couple providing the gametes should detail in writing the disposition of the embryo if they die, divorce or decide not to proceed with implantation.²⁸

But such proposals merely touch the surface of the legal issues raised by

extracorporeal gametes and embryos. The law needs to address the inheritance issues raised by the possibility of freezing gametes and embryos.²⁹ In addition, the question of who shall direct the future of the embryo when the parents disagree needs to be addressed. When an embryo conceived naturally is developing within a woman during the first two trimesters, it is clear that the woman's decision whether or not to terminate it takes precedence over the desires of the man who had provided the sperm.³⁰ The Illinois Attorney General and District Attorney for Cook County in their briefs in Smith v. Fahner assume that the woman's desires will likewise guide the course of the extracorporeal embryo. But it is at least arguable that the man's desires should have equal weight when the embryo's continued existence need not be balanced against the physical and psychological needs of the woman carrying it.

The uses to which embryos may be put, even with the consent of the people providing the gametes, also needs to be considered. Even if a couple's right to privacy to make procreative decisions is held to extend to the use of alternative reproduction, there may still be compelling reasons to prohibit certain applications of the technologies such as the splitting of embryos to create genetically identical individuals³¹ or the use of an animal to gestate the human embryo.³²

The use of embryos for other purposes than treatment of infertile couples also needs to be addressed by the law. For example, the appropriateness of the extension of the fetal research laws to research on embryos needs to be determined.

Protection of the Participants in The New Reproduction Technologies

When the new technologies are used by infertile couples, there are few provisions in current state laws that spell out the rights and responsibilities of the couples who wish to be the societal parents of a child created by alternative reproduction, or the sperm donors, egg donors, embryo donors, surrogates, physicians, laboratory technicians, reproductive biologists, nurses, counselors and others who participate in the new reproduction technologies.

In view of the thousands of births by alternative reproduction each year, the issue of paternity has become an area for immediate legal concern. Many of the children born through these techniques are in legal limbo with their rights inadequately protected. Rather than learning from the problems generated three decades ago by artificial insemination by donor, lawmakers today are continuing to overlook the legal needs of the children conceived through alternative procedures.

In the 1950's and 1960's, when artificial insemination by donor first came into widespread use in this country, a number of cases were brought to establish the children's legal identity. These cases usually occurred as part of a divorce action of a couple who had a child by artificial insemination. In some instances, the husband claimed he should not have to support the child, since they were not genetically related.³³ In others, the wife tried to deny her husband visitation rights based on the same rationale.³⁴

Courts' discomfort with letting a third party into the marriage relationship to solve an infertility problem is perhaps best illustrated by a 1954 Illinois case which said that a woman undergoing artificial insemination had committed adultery even if her husband consented.³⁵ The more recent approach is typified by the California Supreme Court which noted in California v. Sorensen the absurdity of the viewpoint that the sperm recipient commits adultery with the doctor or donor: "Since the doctor may be a woman, or the husband himself may administer the insemination by a syringe, this is patently absurd; to consider it an act of adultery with the donor, who at the time of insemination may be a thousand miles away or may even be dead, is equally absurd."³⁶

Similarly, the court in In re Adoption of Anonymous wrote: "An AID child is not 'begotten' by a father who is not the husband; the donor is anonymous; the wife does not have sexual intercourse or commit adultery with him; if there is any 'begetting' it is by the doctor, who in this specialty is often a woman. The suggestion that the husband might not regard the child as his own has been dispelled by our gratifying experience with adoptive parents. Since there is consent by the husband, there is no

marital infidelity."³⁷

As to the status of the child, a New York court in 1963 held a child conceived through artificial insemination to be illegitimate.³⁸ However, even in cases such as that, where the courts have not viewed children as legitimate, the judges have protected the child, relying upon the husband's consent to the artificial insemination process to hold him liable for support for the child. A subsequent New York case, a decade later, held that the infertile father was indeed the legal father. The court stated: "It serves no purpose whatsoever to stigmatize the AID child; or to compel the parent formally to adopt in order to confer upon the AID child the status and rights of a naturally conceived child."³⁹

Even in cases where the child was not held to be the legitimate child of the husband, the donor has never involuntarily been required to support the child. "The anonymous donor of the sperm cannot be considered the 'natural father', as he is no more responsible for the use made of his sperm than is the donor of blood or a kidney," wrote the court in California v. Sorensen.⁴⁰

Physicians' perception of the uncertain legal status of a child conceived through artificial insemination, however, has led some to undertake actions which are medically inappropriate. Some inseminate the woman with sperm from several donors each cycle to cloud the issue of paternity.⁴¹ This is medically contraindicated since it makes it less likely the insemination will be successful. Even more troublesome is the fact that many practitioners keep no records about which donor they are using for which woman, in part because they are worried the donor might be sued for child support. One survey found that 70% of the practitioners keep no permanent records on donors.⁴² The mixing of sperm and the lack of recordkeeping make it virtually impossible for a doctor to identify, and stop using, a donor who has passed on a genetic defect to an artificial insemination child.⁴³

To clarify the paternity of the child conceived through artificial insemination,

25 states have adopted laws that provide that the artificial insemination offspring is the legal child of the sperm recipient and her consenting husband.⁴⁴

Some of these laws have been long in coming. Despite its judicial precedent 30 years ago of artificial insemination being viewed by the court as adultery, Illinois did not put into effect an artificial insemination law legitimizing the procedure and the child resulting from it until this year.⁴⁵ In 25 states and the District of Columbia, there is no statute yet. And, although courts may be able to reach sound decisions regarding the status of the children, the children should not have to be put through the trauma of litigation to determine who their legal parents are.

In Ohio, where there is no artificial insemination statute, a court was recently called upon to decide whether an ex-husband should have visitation rights to children born through donated sperm. For the children, boys aged 3 and 11, the husband was the only father they knew. He was certainly the psychological father — and they assumed he was the biological father as well. Yet, since there was no statute making the husband the legal father of these boys, the involvement of the court and the publicity surrounding the case threatened to reveal the husband's non-paternity to the children. (Thus, a proceeding presumably designed to determine the children's best interests might actually itself be counter to their interests and do psychological damage to the children).

As the new reproduction technologies have evolved, legislatures have been shortsighted in their attempts to clarify the legal status of the resulting children. In twelve states, the artificial insemination laws provide that if a man donates sperm to a woman who is not his wife, he is not the legal father of the child.⁴⁶ Although these laws were designed to relieve the anonymous sperm donor of parental obligations, they create a barrier to surrogate motherhood, in which the man providing the sperm intends to be the legal father.⁴⁷ There are other obstacles to establishing the parental rights of the man who contracts with a surrogate mother to provide a child for himself and

his wife. In some states, there is the legal presumption that the father of the child is the surrogate's husband.⁴⁸ In addition, men providing the sperm in a surrogate arrangement may not even have standing under current statutes to rebut the presumption in favor of the surrogate's husband's paternity.

Even if all parties — the man providing the sperm, his infertile wife, the surrogate mother and her husband — are in agreement that the couple who contracted for the child should have all rights to the child, there is no specific legal mechanism to assure that this happens. In some states, adoptions have proceeded without problems in the surrogate situation, but in others the children have been left in legal limbo. In 1983, a Kentucky judge refused to recognize an adoption when a surrogate bore a child for pay and transferred custody to the sperm donor and his wife without obtaining placement permission from the Human Resources department as required by statute. The Kentucky judge stressed the need for new laws.⁴⁹

Similarly, in Michigan when an attempt was made to use the paternity laws to give the man providing the sperm the right to a child born to a surrogate mother, the judge rejected the attempt, saying enlargement of the uses of the paternity act was a matter for legislative action, not judicial action.⁵⁰

Most recently the District of Columbia Superior Court also refused to grant a couple's standard adoption application after it was disclosed that the natural mother was a paid surrogate. The court instead ordered a full investigation, emphasizing the need for proof of the child's parentage, and stressed the need in the surrogate situation for an analysis of the suitability of the parents and the adequacy of the consent to the adoption given by the child's natural mother.⁵¹

When a female provides the ovum for another woman, different legal considerations apply. Because the law currently recognizes the woman who gives birth as the child's legal mother, the woman who gives birth after embryo transfer or *in vitro* fertilization using a donor ovum presumptively would have parental rights to the child. Thus, as long

as the woman who receives the donated ovum or embryo wishes to raise the child, the law works in her favor.

But, there will be other instances in which the woman providing an ovum or embryo to be gestated by another woman will intend to have custody of the child after birth. This type of arrangement would be used if the woman providing the genetic material for the child could not carry it to term for some medical reason (for example, due to a hysterectomy, dangerously high blood pressure, or a tendency to spontaneously abort). Since the woman giving birth has legal rights to the child, the woman providing the ovum or embryo might have to adopt the child, even though it is genetically hers. The situation then would be legally analogous to the surrogate mother situation, with payment to the carrier potentially running afoul of the laws prohibiting payment in connection with an adoption. In addition, if the woman serving as a carrier for the child changes her mind and decides to keep the baby, the genetic mother will have little recourse for getting custody of her biological child.

If the new reproduction technologies are to take place and the children to be protected, the laws regarding parentage need to be clarified. Previous statutory approaches to determining parental rights and responsibilities based on either the biological link to the child or the status of the procedure need to be replaced by laws that give legal effect to the parties' preconception intentions.

The deficiencies in attempting to use a biological approach to determining legal paternity when alternative reproduction is used are pointed out by two recent cases. In a California case, an unmarried woman who conceived a child through artificial insemination was ordered by a judge to allow the sperm donor to have visitation rights to the child. The judge was persuaded by the donor's biological tie to the child and the fact that the child had no social father.⁵² But whether it is really in the child's best interest for the sperm donor to have visitation rights is questionable. Empirical evidence does not suggest that having a single parent will unduly harm a child.⁵³

Moreover, it is difficult enough for a divorced couple to decide on how to raise the child, let alone a sperm recipient and a donor who is a stranger.

In a 1981 Illinois case (decided before the recent enactment of an artificial insemination statute), the court was called upon to determine paternity of the resulting child when a woman apparently underwent artificial insemination and had sex with both her husband and her lover on the same day.⁵⁴ The court held that the husband was the legal father, basing its opinion in part on the fact that the husband produced some sperm and thus the court could assume he was the biological father.⁵⁵ If the husband had been completely azoospermic (which is common among men whose wives use donated sperm), the child might have been up for grabs. And the court specifically did not allow the use of HLA-typing to determine which of the three men was actually the biological father.⁵⁶

HLA-typing can determine biological fatherhood with over 90% accuracy. But at the same time that the biological determination of paternity is getting to be more sophisticated, it is getting to be a less appropriate criteria for determining legal rights and responsibilities with respect to the child born through alternative reproduction. Sperm donors and women who donate embryos via embryo transfer can undoubtedly prove their biological link to the child, yet should they be awarded legal rights, when this is contrary to their original intent and when their role in creating the child is such a fleeting one?

The artificial insemination laws were the first statutes governing the new conceptions that moved the inquiry from determining paternity based on a biological tie to the child to determining paternity based on the status of the procedure. Thus, even though the husband of the recipient of donor sperm was not biologically linked to the child, he was the legal father if he consented to the insemination. Similarly, the sperm donor was denied paternal rights once a procedure of this type was entered into.

But the variations on parenthood made possible by the new conceptions belie any

attempt to determine parenthood based on the status of the procedure. The sperm donor may not want to be the legal father in the traditional artificial insemination situation, but the sperm donor may want to be the legal father when artificial insemination is used to impregnate a surrogate mother. The embryo donor may not want to be the legal mother in the embryo transfer situation, but may want to be the legal mother when she uses a surrogate carrier.

To clarify the paternity issue, laws could be enacted to give effect to the intent of the parties prior to the conception. Thus, if the sperm donor agrees to forego parental rights and responsibilities and the sperm recipient and her husband agree to be the societal parents for the child, the sperm donor will not be able to change his mind later and to sue for visitation rights to the child and the couple will be responsible for the care and custody of the child.

Some people will be troubled at the thought that a woman who provides genetic material for a child and gestates the child — that is, a surrogate mother — will be forced to follow through on her original agreement even if she changes her mind during the pregnancy and wishes to keep the child. But if surrogate motherhood is allowed to proceed, this would appear to be the most equitable approach to determining paternity. The arrangement could be viewed as a preconception adoption. The surrogate mother could be held to her agreement unless she could prove that she was unjustly coerced into making the agreement in the first place, an exception to consent that is recognized in the traditional adoption situation as well.⁵⁷ Surrogate mothers will presumably be able to prove coercion less frequently than biological mothers who claim they were forced to give up their children for adoption, however. Since the surrogate mothers are not pregnant when they make their agreements (and thus may not be subject to the same time pressures and emotional pressures as a pregnant woman considering giving up a child for adoption), they generally will not be able to argue convincingly that they were coerced.⁵⁸

If a law recognizes that the intent of the parties governs paternity for the new conceptions child, proof of that intent will become a crucial issue. To avoid the potential psychological harm to the child of courtroom battles over custody, the law should require written evidence of intent before the child is conceived. Such evidence could be required to be part of the doctor's records or could be required to be filed with the state. (Currently, 11 states require that the husband's consent to artificial insemination be filed with the state.⁵⁹)

In the past, the law has been reluctant to recognize private contracts providing for the custody or support of children.⁶⁰ Would a statute on collaborative reproduction allowing establishment of parental rights and responsibilities by agreement be of sound public policy?

The general reasons given for legal presumptions of paternity are to (1) protect against the stigma of illegitimacy, (2) protect the integrity of the family, and (3) provide for the private support of the child.⁶¹ Allowing the parties' preconception intent to govern paternity would meet these policy goals. The intent approach would protect children against the stigma of illegitimacy, a protection they do not have in absence of the statute. Following the intent approach does not damage the integrity of a family. A surrogate mother and her husband are not the family of the child she is bearing for another couple. Starting before conception, all parties have agreed that the child is a part of the latter couple's family.⁶² In addition, since the couple who intend to assume parental rights and responsibilities are clearly identified before the child is conceived, the support of the child is provided for.

An alternative regulatory approach might be to involve adoption agencies in determining the proper placement of children born via the new reproductive technologies. But if a couple's constitutional right to privacy is found to encompass the rights of a couple to use one of the new conceptions, the use of a sperm donor, ovum donor, embryo donor, surrogate mother and surrogate carrier could be viewed as analogous to

the use of a medical treatment to allow a couple to bear a child naturally. Following through on that analogy, the involvement of adoption agencies would seem inappropriate.⁶³

The intent approach could work well once the child is born. But when a surrogate carrier or surrogate mother is used, the intent approach could lead to possible conflicts during the pregnancy. Although the couple would have the right to raise the child, it seems inappropriate to give them control over the woman's behavior during pregnancy — even though the woman's actions could affect the health of "their" child. It would seem that, in order to be constitutional, the surrogate mother or surrogate carrier should retain the right to abort.⁶⁴ If she had received funds to carry the pregnancy, she should be liable to return the money.⁶⁵

It is inappropriate for the government to set detailed standards on a woman's behavior during pregnancy and such standards should not be part of a statute covering surrogates. Extremely harmful behavior of the surrogate during pregnancy — such as drug abuse — could be grounds for a lawsuit against the woman if the child is injured as a result.⁶⁶ Although the couple might feel such a suit is a hollow protection since surrogates would not generally have the funds to satisfy an award of damages,⁶⁷ legislation controlling a woman's behavior during pregnancy would be virtually unenforceable (or at the least, socially repugnant) because of its intrusive nature.⁶⁸ The best protection for the couples in this respect lies in adequate screening of the surrogates before the pregnancy.

The intent approach has already been taken in the Washington artificial insemination law.⁶⁹ Under that law, when a man donates sperm to a woman who is not his wife, he is not the legal father unless he and the woman agree in writing that he will be the legal father.

In addition, at least one bill under consideration would apply the intent approach to various forms of alternative reproduction. A Michigan legislator, Representative

Richard Fitzpatrick, has drafted a bill to be introduced next fall, which covers a wide variety of reproductive technologies (artificial insemination, egg donation, embryo adoption, artificial embryonation, surrogate gestation and embryo freezing). The current draft of the bill takes the approach of allowing the parties' intent to govern paternity. Before one of the reproduction technologies can take place, the donor(s) and couple must be counseled by a marriage counselor, psychologist or psychiatrist and they must record their intentions. The procedure must take place within 30 days after the counseling and signing of the written agreement. Additional provisions govern the use of surrogates. Surrogate mothers and surrogate carriers agree to abide by reasonable medical instructions during pregnancy, but are not required to abort the fetus. Within 24 hours after the surrogate gives birth, the various parties, including the child, must undergo the performance of blood or tissue typing tests to determine paternity. If the tests show that the man who contracted to father a child by the surrogate is not the father, the surrogate assumes parental rights and responsibilities.

Assuring the Safety of the New Reproduction Technologies

If alternative reproduction is to be allowed, an attempt should be made to assure that it is undertaken in a safe manner so that the parties will not be harmed. Sperm donation is a simple and painless procedure, but ova donation is more risky physically. The woman may need to undergo hormone treatment and a laparoscopy under anesthesia will generally be necessary to recover the ova. Consideration should be given to whether the physical well-being of the ova donor seems to be sufficiently protected under current medical standards.

The health of the gamete recipients and the children conceived through alternative reproduction have not been well protected under current practices. Some women who have been inseminated have contracted venereal disease from the sperm.⁷⁰ In addition, children have been born with genetic defects that were passed on by the sperm donor.⁷¹

Both the American Fertility Society (AFS)⁷² and the Reproductive Council of

the American Association of Tissue Banks (AATB)⁷³ have developed extensive guidelines regarding the proper screening of donors to avert such tragedies. The AFS guidelines recommend culturing sperm samples for gonorrhea and suggest that doctors investigate the donor's family history and reject prospective donors with a family history of mental retardation, neurologic disorders, unexplained deaths under age thirty, or significant congenital defects. The AFS also suggests that the Tay-Sachs trait should be screened for in Jewish donors and sickle cell trait should be screened for in black donors.

The AATB Reproductive Council standards are even more detailed. They recommend selecting donors on the basis of a "personal, physical and genetic examination and history of individuals as well as an in-depth semen analysis which includes microbial screening".⁷⁴ Among the specific guidelines is a recommendation that each sperm sample from the donor be tested for gonorrhea, with periodic analysis of the donor's blood for syphilis and hepatitis. They also mandate rejection of a potential sperm donor if he is a carrier of any of 19 specified disorders, if his risk of producing a child with a genetic defect is greater than one percent, if he is employed in a job involving chemical or radiation exposure, or if he is an alcohol or drug abuser.

Despite the existence of these detailed guidelines, screening of sperm donors is lax. A national survey of infertility specialists offering artificial insemination found that only 29% performed biochemical testing other than blood-typing on the donor — and most of this testing was for infectious diseases, not genetic defects.⁷⁵ In addition, as noted earlier, 70% of the practitioners kept no permanent records about the donors⁷⁶ making it difficult to trace a donor who has passed on a disease or defect and to cease using him. Some practitioners argue that they do not screen donors through blood tests due to the cost, but couples should at least be informed of the availability of such testing and asked if they wish it to be undertaken.⁷⁷

The medical standards regarding donor screening are not sufficient to protect the parties involved. There is no reason to believe that the other reproductive

technologies involving donor gametes or embryos or surrogate gestation, once they are put to widespread use, will entail sufficient screening either.

Only a few jurisdictions regulate the screening of participants in alternative reproduction. A New York City ordinance⁷⁸ provides that carriers of genetic diseases or defects and men suffering from venereal disease or tuberculosis cannot be sperm donors. It also provides that the sperm donor and recipient must have compatible Rh factors. An Oregon law provides that a person who knows he has a genetic defect or venereal disease may not be a sperm donor.⁷⁹ A proposed Washington, D.C. ordinance⁸⁰ introduced by Councilman John Ray mandates screening of sperm donors and the proposed Michigan law requires genetic screening of all gamete donors. If gametes or embryos are donated to infertile couples (either with or without freezing), laws are necessary to assure that the individuals who provide the gametes are in good health. But such a stipulation is only one of the factors necessary to assure that children are not harmed by the new conceptions.

With all the alternative reproductive techniques, the questions can be asked: Do the techniques themselves cause any harm to the children? And, if so, is the magnitude of the harm so extensive and unavoidable that the technique should be banned or the users of the technique should be held strictly liable for damages?⁸¹ When *in vitro* fertilization first came into use, such arguments were made, but based on the births to date following *in vitro* fertilization there does not seem to be an increased proportion of anomalies.

With respect to artificial insemination, a 1983 French study of 2,052 artificial insemination children found a lower malformation rate than among children conceived normally.⁸² But there was some evidence of a higher than average number of children with the chromosomal defect of trisomy. Perhaps the increase in trisomy was due to the advanced age of the women giving birth through artificial insemination compared with the population at large (due in part to the delay entailed by the investigation and

treatment of the infertility problem). Offering women the option of having karyotyping of themselves and the donors and amniocentesis during the pregnancy would help prevent or identify some of the trisomy conceptions.

Surrogate gestation, embryo transfer, and other newer forms of alternative reproduction have not produced enough births to be able to gauge their effects on the offspring. However, it has been speculated that freezing might cause some damage to the embryo due to the mutagenic effects of the background radiation.⁸³ Information should be accumulated about the physical effects of the new means of reproduction on the children they produce so that sound regulation can be developed.

Another potential harm to the child could occur as a result of the creation, through alternative reproduction, of numerous siblings or half-siblings. This could cause two potential problems: the overrepresentation of certain individuals in society's gene pool and the possibility of unwitting incestuous marriages. Although a surrogate mother is naturally limited in the number of children she could create, a woman who is given hormones to induce ovulation could provide multiple ova or embryos each month. In addition, human embryos could be split to create several genetically identical individuals (as has already been done with animal embryos⁸⁴), thus further increasing the number of children a woman could create through the new conceptions.

The potential problems are most pronounced with artificial insemination. When a donor provides sperm to a sperm bank, the sample is generally divided into three or more donations. If the donor provides sperm two times a week, he could create at least 156 children a year.⁸⁵

There are no legal regulations limiting the number of pregnancies a sperm donor, egg donor, or embryo donor could create. A 1979 study revealed that 88.4% of practitioners set no limits on how many times sperm donors could be used.⁸⁶

The American Fertility Society guidelines suggest that a donor should be limited to fifteen successful pregnancies. The American Association of Tissue Banks' proposed

guidelines suggest that the overuse of a donor in one particular geographical area is to be avoided in order to limit the possibility of consanguineous marriages.

The Royal College of Obstetricians and Gynaecologists Ethics Committee on In Vitro Fertilisation and Embryo Replacement on Transfer established guidelines regarding embryos to prevent the creation of siblings who are unknown to one another.⁸⁷ The guidelines provide that once a successful pregnancy has been achieved for a couple through in vitro fertilization, any remaining frozen embryos should not be donated to another infertile couple.

The proposed Washington, D.C. ordinance is the only pending legislation that touches on this issue. It provides that a donor's sperm may be used to achieve pregnancies in only one woman. That woman may bear several children from the donor's sperm, but the donor's sperm cannot be used in other women.

The psychological effects of alternative reproduction on the parties need to be considered as well -- in particular to assess claims that the psychological harm to a participant (such as a surrogate mother) is a sufficient reason to ban a particular procedure. The new reproduction technologies have emotional ramifications for the couples, the donors, and the children born through the techniques.⁸⁸ The use of a donor or a surrogate mother replaces the biological input of one of the spouses in the couple. That individual may feel left out and suffer psychologically as a result.

The donor of a gamete or the woman who provides a womb for gestation may also be psychologically disturbed by participation in the process. Some surrogate mothers go through a period of depression and grieving after the surrendering of the infant.⁸⁹ Likewise, some sperm donors later feel remorse about the fact that they have created children whom they may never see. Individuals who are not direct participants in the process also may be affected. The parents of sperm donors in some instances have felt disturbed that their sons have "given away" their "grandchildren". The existing children of the egg donor, sperm donor or surrogate may fear abandonment.

The Royal College of Obstetricians and Gynaecologists Ethics Committee on In Vitro Fertilisation and Embryo Replacement or Transfer recommended against the use of surrogate carriers and surrogate mothers on the grounds that these women cannot predict beforehand what their attitudes toward the children will be and the relinquishment might cause emotional stress. Yet a policy of banning a particular alternative reproduction based on scanty psychological evidence is inappropriate.

Sound empirical data needs to be collected on the psychological ramifications of all the technologies. It is inappropriate to condemn one type of donation (womb rental) and not the others (ovum or sperm donation) without exploring the effects on the donors in all instances. How are they affected by their experiences at the time — and years later? How does it influence their relationships with the children they raise? These are the types of questions that need to be answered.

The psychological effects of the new technologies on the resulting children also need to be explored. Some who were conceived through artificial insemination and are now in their 20's and 30's feel that they have suffered emotionally as a result of being created through these means. Like adoptees, some artificial insemination children feel that, for reasons of their psychological and medical well-being, they need to learn about or meet their biological fathers, the sperm donors.⁹⁰ The open questions regarding the psychological effects on the child of the new conceptions include whether problems are caused by the use of a donor or surrogate per se; by keeping the extra parents' involvement secret;⁹¹ by informing the child about the involvement of the donor or surrogate;⁹² by allowing the child to meet the donor or surrogate; by payment to the donor or surrogate; by eugenic selection of the gamete donors;⁹³ or by the creation of genetically identical individuals through the splitting of embryos.

The proposed Michigan legislation requires that, before alternative reproduction takes place, a marriage counselor, psychologist or psychiatrist counsel the societal parents who will raise the child on "the consequences and responsibilities of parenthood"

achieved through the technique they will undertake. The counselor must certify that the couple understand the techniques and are prepared to undertake parental responsibilities. A counselor must also certify that the gamete donor or the surrogate is sufficiently aware of the potential psychological consequences of his or her consent. A proposed Australian law similarly requires counseling by approved counselors of couples who undergo in vitro fertilization using their own gametes or donated gametes and for donors who provide gametes for in vitro fertilization.⁹⁴

Counseling of individuals participating in the new reproduction technologies is important, but the advisability of mandating counseling needs to be closely assessed, especially since requiring counseling by particular types of health care professionals will increase the cost to the consumer of already expensive procedures. Is enough known about the psychological ramifications for counseling to be required? Is it clear that only certain licensed or approved individuals are capable of providing counseling or might the doctor, his or her nurse, or a written statement be sufficient?

While various legislative proposals suggest counseling for the adults involved in alternative reproduction, they approach the psychological needs of the child in a different way. Indirectly, the Michigan bill concerns itself with the child's well-being by requiring a counselor's assessment that the societal parents are able to fulfill parental responsibilities. More directly, the bill provides that when the child reaches age 18, he or she is entitled to information filed with the state showing that alternative reproduction was used, and naming and providing medical information about the parties involved, including any gamete donor or surrogate. The proposed Washington, D.C. ordinance governing artificial insemination would allow children when they reach 18 years of age to learn the genetic and medical history of the donor, but would not provide the name of the donor.

A California assemblyman, Steve Pearce, is considering introducing a bill that would establish a registry (similar to the adoption registries) so that sperm donors and

the children they create can attempt to contact each other.⁹⁵ Already, two private organizations have established such registries.⁹⁶

Protection of Society

The child of the new reproduction technologies is not just the child of the couple who will raise him, the donors or surrogate who provide biological input, or the scientists or physicians who help create him. He is society's child because his birth portends changes that influence society as a whole. Thus, society's interests need to be taken into consideration when policies are set in this area. In some instances, the effects of certain uses of the new reproduction technologies may be sufficiently detrimental to society that they should be restricted or banned.

A very basic question regarding the new reproductive technologies is the financial cost to society of their use. Applying the logic of the U.S. Supreme Court's abortion funding decision,⁹⁷ even if a constitutional right to use the new reproduction technologies were recognized, there would be no obligation on the part of the government to finance their use.

There might be an obligation for the government to pay for the maintenance of frozen embryos if they were abandoned (due to their parents' death, divorce, or disinterest). In Michigan, the state was forced temporarily to provide foster care for a child when the surrogate mother and the man who had contracted for the child both said they did not want custody of the child.⁹⁸ The proposed Michigan legislation deals with this issue by requiring that participants in the new reproductive technologies post a surety bond to indemnify the state. It also provides that, in a surrogate situation, if a societal father and societal mother die, the surrogate mother or surrogate carrier must assume parental responsibilities for the child.

Another societal concern is the possibility that the new reproductive technologies will be used for eugenic purposes. The late Nobel Prize winner Hermann J. Muller advocated such an approach. "Foster pregnancy, which is already possible, will become

socially acceptable and even socially obligatory," he asserted. "It will seem wrong to breed children who mirror parents' peculiarities and weaknesses. In the future, children will be produced by the union of ovum and sperm, both derived from persons of proved worth, possibly long deceased, and who exemplify the ideals of the foster-parents."⁹⁹ Already, some couples are choosing sperm donors or surrogate mothers based on eugenic concerns — for example, choosing a donor who has won a Nobel Prize or a surrogate with musical ability. And some commentators suggest that the government might have the right to force eugenics on a societal scale.

A National Academy of Sciences Committee pointed out the problems that could be raised by a sweeping application of eugenics: "[W]ho will decide what is desirable? How much genotypic and phenotypic variability would be optimal in the human society? Who would dare to prohibit procreation to a majority of men and women, limiting this activity only to an elite group? And to whom would society entrust such decisions?"¹⁰⁰ Even if a societal consensus could be reached about which genetic traits should be favored, mandating the use of egg and sperm donors with those traits may actually injure rather than improve the gene pool by diminishing genetic variety and possibly proliferating unwanted recessive genes of donors chosen for other traits.

No laws, proposed legislation or ethical guidelines currently speak directly to the issue of eugenics. The proposed Michigan legislation limits the use of alternative reproduction to couples whose doctors certify they have an infertility problem or a genetic defect which they do not wish to pass on. Such a provision may prohibit fertile, normal couples from using alternative reproduction to enhance their children's genetic makeup. The proposed Washington, D.C. artificial insemination ordinance and a companion bill on surrogate motherhood attempt to discourage private eugenics by prohibiting payment of sperm donors or surrogates. Councilman John Ray, who drafted the bills says this is to prevent clinics from "offering the sperm of Robert Redford or Muhammad Ali."

Another use of the new conceptions that may be socially troubling is the cross-fertilization of humans and other species, such as primates. Human/animal creations could be used to provide organs for transplants or to undertake dangerous or demeaning jobs.¹⁰¹ But such an approach has been criticized as ethically unacceptable "for the human component would be condemned to a situation unworthy of it."¹⁰² No proposed or existing American legislation covers this situation, but the British Medical Research Council has recommended that research on interspecies fertilization should be permissible only if the embryos are not allowed to develop beyond the early cleavage stage.¹⁰³

Looking Ahead

The new conceptions raise the need for forward-looking laws that determine the paternity of resulting children, that set forth the rights and responsibilities of the participants in the process, that provide guidelines regarding the safe and efficacious undertaking of the procedures and that make provision for the care of extracorporeal embryos. The setting of policy in this area requires empirical study of the medical, psychological, and financial effects of the techniques on the participants, on the resulting children, and on society. To that end, a registry or clearinghouse of information should be established.¹⁰⁴ In addition, an on-going Commission should be established to evaluate existing information on the technologies, with special attention to their effects on society. The various mechanisms established to oversee the new conceptions to date do not provide a means of assessing the societal effects of the techniques. The proposed laws do not directly address it. The ethical guidelines created by the medical profession do not take it into consideration. The Institutional Review Boards ignore societal ramifications as well.¹⁰⁵ A Commission on the new reproductive technologies could be a means to assure that the immediate goal of creating a child for a couple who desperately want one does not overshadow an assessment of the overall risks and benefits of the new conceptions.

FOOTNOTES

1. See, e.g., Harry Nelson and Edwin Chen, "Orphan Embryos Raise Legal, Ethical Questions," Los Angeles Times (June 19, 1984); UPI, "Surrogate Mom Feels Bad, But Won't Give Baby Away," Columbus Citizen-Journal 2 (Wednesday, November 9, 1983); E. J. Dionne, Jr., "A French Widow Sues to Get Husband's Sperm from Bank," New York Times (July 2, 1984); and Bill Billiter, "Quest for Identity Hinges on Finding Real Father," Los Angeles Times (December 5, 1982).
2. Department of Health, Education, and Welfare, Office of the Secretary: Protection of Human Subjects; HEW Support of Human In Vitro Fertilization and Embryo Transfer: Report of the Ethics Advisory Board, 44 Federal Register 35033, 35058 (1979).
3. Yale Law professor Fred Rodell aptly pointed out the distinction: "If a British barrister of two hundred years ago were suddenly to come alive in an American court-room, he would feel intellectually at home Imagine, by contrast, a British surgeon of two hundred years ago plopped into a modern hospital operating room. He would literally understand less of what was going on than would any passer-by in from the street at random." Fred Rodell, Woe Unto you, Lawyers! 30 (New York, Pageant Press, Inc. 1957).
4. See, e.g., John A. Robertson, "Procreative Liberty and the Control of Conception, Pregnancy and Childbirth," 69 Virginia L. Rev. 405 (1983).

5. Ariz. Rev. Stat. Ann. §36-2302 (Supp. 1982-83); Ark. Stat. Ann. §82-436 to -441 (Supp. 1983); Cal. Health & Safety Code §25956 (West Supp. 1983); Fla. Stat. Ann. §390.001 (6), (7) (West Supp. 1983); Ill. Ann. Stat. ch. 38 §81, -32, -32.1 (Smith-Hurd Supp. 1983-84); Ind. Code §35-1-58.5-6 (1979); Ky. Rev. Stat. Ann. §436.026 (1975); La. Rev. Stat. Ann. §14:87.2 (West 1974); Me. Rev. Stat. Ann. tit. 22 §1593 (West 1980); Mass. Ann. Laws ch. 112 §12J (Supp. 1983); Mich. Comp. Laws Ann. §§333.2685-2692 (West 1980); Minn. Stat. Ann. §145.421 to .422 (West Supp. 1982); Mo. Ann. Stat. §188.037 (Vernon Supp. 1983); Mont. Code Ann. §50-20-108(3)(1981); Neb. Rev. Stat. §28-342-346 (1979); N.M. Stat. Ann. §24-9 A-1. et seq (1978); N.D. Cent. Code §14-02.02-01 to -02 (1981); Ohio Rev. Code Ann. §2919.14 (Baldwin 1982); Okla. Stat. Ann. tit.63 §1-735 (West Supp. 1982-83); Pa. Stat. Ann. tit. 18 §3216 (Supp. 1983-84); R.I. Gen. Laws §11-54-2 (Supp. 1982); S.D. Comp. Laws Ann. §34-23A-17 (1977); Tenn. Code Ann. §39-308 (Supp. 1982); Utah Code Ann. §76-7-310 (1978); and Wyo. Stat. §35-6-115 (1977).

6. Ariz. Rev. Stat. Ann. §36-2032 (Supp. 1982-83); Ky. Rev. Stat. Ann. §436.026 (1975) and §311.720 (5), (6) (1983); La. Rev. Stat. Ann. §14:87.2 (West 1974); Mass. Ann. Laws chap. 112 §12J (Supp. 1983); Mich. Comp. Laws Ann. §§333.2685 to .2692 (West 1980); Mo. Ann. Stat. §188.037 and §188.015 (5) (Vernon Supp. 1983); N.D. Cent. Code §14-02.2-01 to -02 (1981); Ohio Rev. Code Ann. §2919.14 (Baldwin 1983); Okla. Stat. Ann. tit.63 §1-735 and §1-730 (West Supp. 1982-83); Pa. Stat. Ann. tit. 18 §3216 and §3203 (Supp. 1983-84); and R.I. Gen. Laws §11-54-2 (Supp. 1982).

7. Me. Rev. Stat. Ann. tit. 22 §1593 (West 1980); Mass. Ann. Laws Chap. 112 §12J (Supp. 1983); Mich. Comp. Laws §333.2685 to .2692 (West 1980); N.D. Cent. Code

§14-02.2-01 to -02 (1981); R.I. Gen. Laws §11-54-2 (Supp. 1982); and Utah Code Ann §76-7-310 (1978).

8. Ariz. Rev. Stat. Ann. §36-2302 (Supp. 1982-83); Fla. Stat. Ann. §82-436 to -441 (Supp. 1983); Ind. Code §35-1-58.5-6 (1979); La. Rev. Stat. Ann. §14:87.2 (West 1974); Me. Rev. Stat. Ann. tit. 22 §1593 (West 1980); Mass. Ann. Laws chap. 112 §12J (Supp. 1983); Mich. Comp. Laws Ann. §§333.2685 to .2692 (West 1980); Mo. Ann. Stat. §188.037 (Vernon Supp. 1983); Mont. Code Ann. §50-20-108 (3) (1981); Neb. Rev. Stat. §28-342, -346 (1979); N.D. Cent. Code §14-02.2-01 to -02 (Allen Smith 1981); Ohio Rev. Code Ann. §2919.14 (Baldwin 1983); Okla. Stat. Ann. tit. 63 §1-735 (West Supp. 1982-83); Pa. Stat. Ann. tit. 18 §3216 (Supp. 1983-84); R.I. Gen. Laws §11-54-2 (Supp. 1982); Utah Code Ann. §76-7-310 (Allen Smith 1978); and Wyo. Stat. §35-6-115 (1977). This list includes both statutes that specifically apply to embryos and statutes which neglect to define "fetus" or the term used to refer to the subject of research and might be interpreted to include preimplantation embryos. For a more detailed explanation of the reach of the fetal experimentation laws, see Lori B. Andrews, "The Stork Market: The Law of the New Reproduction Technologies," 70 American Bar Association Journal 50 (August 1984).
9. Me. Rev. Stat. Ann. tit. 22 §1593 (West 1980); Mass. Ann. Laws ch. 112 §12J (a) IV (Supp. 1982); Mich. Comp. Laws Ann. §333.2690 (West 1980); Neb. Rev. Stat. §28-342 (1979); N.D. Cent. Code §14-02.2-02 (Allen Smith 1981); R.I. Gen. Laws §11-54-2 (f) (Supp. 1982); and Wyo. Stat. §35-6-115 (1977). Under the laws of Nebraska and Wyoming this provision only applies to the use of an aborted embryo. Yet, the flushing techniques used to retrieve an in vivo embryo for embryo transfer appears to fall within the definition of an abortion. Thus, the Nebraska and Wyoming laws could be read to prohibit a woman from participating in embryo

transfer or embryo freezing after in vivo fertilization but would not prohibit her from allowing an embryo to be frozen after in vitro fertilization since no abortion-like procedure is involved in the latter technique.

10. Maine, Massachusetts, Michigan, Rhode Island, and North Dakota.
11. Me. Rev. Stat. Ann. tit. 22 §§1593 (West 1980); Mass. Ann. Laws. ch. 112 §12J(a) IV (Supp. 1982); Mich. Comp. Laws Ann. §333.2690 (West 1980); Neb. Rev. Stat. §28-342 (1979); N.D. Cent. Code §14-02.2-02 (Allen Smith 1981); Ohio Rev. Code Ann. §2914 (Baldwin 1983); Okla. Stat. Ann. tit. 63 §1-735A (West Supp. 1982-83); R.I. Gen. Laws §11-54-2 (f) (Supp. 1982); Utah Code Ann. §76-7-311 (Allen Smith 1978); and Wyo Stat. §35-6-115 (1977). Again, the distinction discussed in note 9, supra, applies. Nebraska, Ohio, Oklahoma, and Wyoming cover only aborted embryos.
12. See, e.g., Ala. Code §26-10-8 (1975); Ariz. Rev. Stat. Ann. §8-126(c) (1974); Cal. Penal Code §273(a) (West 1970); Colo. Rev. Stat. §19-4-115 (1974); Del. Code Ann. tit. 13 §928 (1981); Fla. Stat. Ann §63.212(1)(b) (West Sup. 1983); Ga. Code Ann. §19-8-19 (1982); Idaho Code §18-1511 (1979); Ill. Rev. Stat. ch 40 §§1526, 1701, 1702, (1981); Ind. Code Ann. §35-46-1-9 (Burns Supp. 1983); Iowa Code Ann. §600.9 (West 1981); Ky. Rev. Stat. §199.590 (2) (1982); Md. Ann. Code art. 16 §83 (1981); Mass. Ann. Laws ch 210 §11A (Michie/Law Coop. 1981); Mich. Comp. Laws Ann. §710.54 (West Supp. 1983-84); Nev. Rev. Stat. §127.290 (1983); N.J. Stat. Ann. §9:3-54 (West Supp. 1983-84); N.Y. Soc. Serv. Law §374(6) (McKinney 1983); N.C. Gen. Stat. §48-37 (Supp. 1981); Ohio Rev. Code Ann. §3107.10(A) (Page 1982); S.D. Codified Laws Ann. §25-6-4.2 (Supp. 1983); Tenn. Code Ann. §36-136 (Supp. 1983); Utah Code Ann. §76-7-203 (1978); and Wis. Stat. Ann. §946.716 (1982). However, since the statutes in the states of Arizona, California, Florida, Illinois, Iowa, and New Jersey exempt stepparents from the statutory reporting requirements for payment

in connection with an adoption, it may be possible to circumvent the ban in these states so long as the man who provided the sperm can prove that he is the biological father and thus that his adopting wife will be stepparent.

13. Doe v. Kelley, 106 Mich. App. 169, 307 N.W. 2d 438 (1981), cert. denied, 459 U.S. 1183 (1983). The court held the payment prohibition in the adoption code did not directly prohibit the surrogate arrangement, but prevents the couple from paying the surrogate if they want to use the adoption code to change the child's legal status.

14. Kentucky v. Surrogate Parenting Associates, Inc., 10 Family Law Reporter 1105 (Ky. Cir. Ct., Franklin Cty. 1983) No. 81-CI-0121 (October 26, 1983). This case is distinguishable from Doe v. Kelley, however, since the Kentucky law did not prohibit payment in connection with the termination of parental rights and this was the procedure that the surrogate mother used to sever her rights to the child and turn the child over to the biological father and his infertile wife. Thus, while the Michigan case dealt with a specific legislative policy against payment in connection with an adoption, the Kentucky court was faced with the more abstract question of whether payment in connection with the termination of parental rights, an activity that did not fall within a legislative ban, should nevertheless be prohibited as a violation of public policy against baby selling or as an attempt to circumvent the Kentucky law (Ky. Rev. Stat. §199.590(2) (1982)) prohibiting payment in connection with an adoption. It concluded that no such public policy could be read into the statutes but a specific legislative ban on payments for termination of parental rights was necessary before surrogate motherhood arrangements would violate Kentucky law. Id. at. 1106.

15. The attempts to ban surrogate motherhood are not unlike the attempt, three decades ago, to prohibit artificial insemination by donor. A bill proposed in the Ohio legislature in the 1950's would have subjected all those who participated in artificial insemination to a \$500 fine and one to five years imprisonment. Mary Ann B. Oakley, "Test Tube Babies: Proposals for Legal Regulation of New Methods of Human Conception and Prenatal Development," 8 Family Law Quarterly 385, 386, n. 10 (1974).

16. Ill. Ann. Stat. ch.38 §81-26(7) (Smith-Hurd Supp. 1983-84).

17. Ill. Rev. Stat. ch.23 §2354.4 (1981).

18. No. 82 c4324 (N.D., Ill. 1982).

19. See Lori B. Andrews, "Legal Issues Raised by In Vitro Fertilization and Embryo Transfer" 11, 12, in Don Wolf and Martin M. Quigley, eds., Human In Vitro Fertilization and Embryo Transfer (New York, Plenum Press, 1984).

20. See Dionne, supra n. 1.

21. Id. On August 1, 1984, a French court ruled that the woman should be allowed to be inseminated with her husband's sperm. UPI, "Widow Wins Right to Dead Mate's Sperm," Chicago Sun-Times 5 (August 2, 1984).

22. No. 74-3558 (S.D.N.Y. 1978).

23. Mrs. Del Zio was awarded \$50,000 damages for emotional distress, however.
24. See, Nelson and Chen, supra. n. 1.
25. The physicians may have a conflict of interest. They might not wish to bring the embryos to term for fear that they will have been harmed by the freezing process, since the embryos were frozen several years ago, before a successful approach to freezing had been developed. The next of kin may have a conflict of interest as well, since he may prefer not to have the embryos brought to term in case they would challenge his inheritance rights.
26. American Fertility Society, "Ethical Statement on In Vitro Fertilization," 41 Fertility and Sterility 12 (1984).
27. C. Levine, "In Britain and Australia, New In Vitro Guidelines," 13 Hastings Center Report 2 (1983).
28. Substitute for Michigan House Bill 4114, Draft 2, as amended.
29. See, e.g., Winthrop P. Thies, "A Look to the Future: Property Rights and the Posthumously Conceived Child," 110 Trusts and Estates 922 (1971).
30. See, e.g., Planned Parenthood v. Danforth, 428 U.S. 52 (1976).

31. See text at n. 84, *infra*.
32. This possibility is discussed in Robert T. Francoeur, Utopian Motherhood: New Trends in Human Reproduction (Garden City, New York, Doubleday and Company, Inc., 1970).
33. See, e.g., Anonymous v. Anonymous, 41 Misc. 2d 886, 246 N.Y.S. 2d 835 (Sup. Ct. 1964).
34. See, e.g., Strnad v. Strnad, 190 Misc. 786, 78 N.Y.S. 2d 390 (Sup. Ct. 1948); New York v. Dennett 15 Misc. 2d 260, 184 N.Y.S. 2d 178 (Sup. Ct. 1958).
35. Doornbos v. Doornbos, 23 U.S.L.W. 2303 (Super. Ct. Ill. 1954), appeal dismissed on procedural grounds, 12 Ill. App. 2d. 473, 139 N.E. 2d 844 (1956).
36. California v. Sorensen, 68 Cal. 2d 280, 501, 437 P. 2d 495, 66 Cal. Rptr. 7 (1968).
37. In re Adoption of Anonymous, 74 Misc. 2d 99, 345 N.Y.S. 2d 430, 434-35 (Sur. Ct. 1973).
38. Gursky v. Gursky, 39 Misc. 2d 1083, 242 N.Y.S. 2d 406, 411 (Sup. Ct. 1963).
39. In re Adoption of Anonymous, 345 N.Y.S. 2d at 435 (Surr. Ct. 1973).
40. California v. Sorensen, 437 P. 2d at 498.

41. Lori B. Andrews, "Embryo Technology", Parents 63, 65 (May 1981).
42. Martin Curie-Cohen, Lesleigh Luttrell, and Sander Shapiro, "Current Practice of Artificial Insemination by Donor in the United States," 300 New England Journal of Medicine 585, 588 (1979).
43. Reports of genetic defects in children who were conceived through artificial insemination include William G. Johnson, Robin C. Schwartz, and Abe M. Chutorian, "Artificial Insemination by Donors: The Need for Genetic Screening," 304 New England Journal of Medicine 755 (1981) and David N. Shapiro and Raymond J. Hutchinson, "Familial Histiocytosis in Offspring of Two Pregnancies After Artificial Insemination," 304 New England Journal of Medicine 757 (1981).
44. Alaska Stat §25.20.045 (Supp. 1982); Ark. Stat. Ann. §61-141 (1971); Cal. Civ. Code §7005 (West Supp. 1983); Colo. Rev. Stat. §19-6-106 (1978); Conn. Gen. Stat. §§45-69f to 69n (1981); Fla. Stat. Ann. §742.11 (West Supp. 1983); Ga. Code Ann. §§74-101.1, -9904 (1982); Ill. Ann. Stat. ch. 40 §1451 et. seq. (Smith-Hurd Supp. 1983-84); Kan. Stat. Ann. §§23-128 to -130 (1981); La. Civ. Code Ann. Art. 188 (West Supp. 1983); Md. Est. & Trusts Code Ann. §1-206(b) (1974); and Md. Health-General Ann. Code §20-214 (1982); Mich. Comp. Laws Ann. §333.2824 (1980) and §700.111 (1980); Minn. Stat. Ann. §257.56 (1982); Mont. Rev. Code Ann. §40-6-1-6 (1981); Nev. Rev. Stat. §126.061 (1979); N.Y. Dom.Rel. Law §73 (McKinney 1977); N.C. Gen. Stat. §49A-1 (1976); Okla. Stat. Ann. tit. 10, §§551-553 (West Supp. 1982-83); Or. Rev. Stat. §§109.239, .243, .247, 677.355, .360, .365, .370 (1981); Tenn. Code Ann. §53-446 (Supp. 1981); Tex. Fam. Code Ann. §12.03 (Vernon 1975); Va. Code §64.1-7.1 (1980); Wash. Rev. Code Ann. §26.26.050 (West Supp. 1983-84); Wis. Stat.

Ann. §767.47(9) (West 1981), §891.40 (West Supp. 1982-83); and Wyo. Stat. §14-2-103 (1978).

45. Ill. Ann. Stat. ch. 40 §1451 et. seq. (Smith-Hurd Supp. 1983-84).
46. Cal. Civ. Code §7005(b) (West Supp. 1983); Colo. Rev. Stat. §19-6-106 (2) (1978); Conn. Gen. Stat. §45-69j (1981); Ill. Ann. Stat. ch. 40 §1453(b) (Smith-Hurd Supp. 1983-84); Minn. Stat. Ann. §257.56(2) (1982); Mont. Code Ann. §40-6-106(2) (1981); Nev. Rev. Stat. §126.061(2) (1979); Or. Rev. Stat. §109.239(1)(2) (1981); Tex. Fam. Code Ann. §12.03(b) (1975); Wash. Rev. Code Ann. §26.26.050(2) (West Supp. 1983-84); Wis. Stat. Ann. §891.40(2) (West Supp. 1982-83); Wyo. Stat. §14-2-103(b) (1978).
47. When a California surrogate mother who was inseminated with a man's sperm decided to keep the child and the man sued for custody of the child, the judge in a statement to reporters indicated that such a provision in California's artificial insemination law might prevent the man from getting custody. The application of the provision was not litigated, however, since the man withdrew the suit. Lois Timmick, "Surrogate Mother Wins Fight to Keep Custody of Infant Son," Los Angeles Times, Section I, at 3 (June 5, 1981).

A suit now pending in California challenges the application of the artificial insemination provision to situations involving surrogate mothers. Handel v. California State Dept. of Social Services, C500854 (filed June 5, 1984).
48. Comment, "Surrogate Motherhood in California: Legislative Proposals", 18 San Diego L. Rev. 341, 354-356 (1981).

49. In re Baby Girl, No. 83AD (Cir. Ct. March 8, 1983), 9 Family Law Reporter 2348 (April 5, 1983).
50. Syrkowski v Appleyard, Civ. Action 81 122 DP (Cir. Ct. Mich. 1981), aff'd, 122 Mich. App. 506, 333 N.W. 2d 90 (1983).
51. In re R.K.S., 10 Family Law Reporter 1383 (Super. Ct. D.C., April 13, 1984).
52. Interview with Roberta Achtenberg, Lesbian Rights Project, January 1984.
53. Moreover, adoptions by unmarried individuals are possible in all fifty states. Barbara Kritchevsky, "The Unmarried Woman's Right to Artificial Insemination: A Call for An Expanded Definition of Family," 4 Harvard Women's Law Journal 1 (1981).
54. Happel v. Mecklenburger, 101 Ill. App. 3d 107, 427 N.E.2d 974 (1981).
55. Id. at 113. The paternity laws create a biological "fiction" that a child born to a married woman is the child of her husband unless he was completely sterile or away from home for a long period during the time she conceived. The judge in this case held a low sperm count was not clear and convincing evidence sufficient to rebut the paternity presumption.
56. Id. at 114. The court denied the plaintiff's request for an order of HLA testing of the parties, but assumed no exclusion of the true biological father would be determinable from the test. Since no definite exclusion could be established (according to the judge) the test results would not be admissible evidence.

57. See, e.g., Re Adoption of Robin, 571 P.2d 850 (Okla. 1977), in which the court held a mother's written consent to her child's adoption was obtained by duress after her stepmother threatened to kill her if she refused. A statute might also attempt to elucidate what qualifies as coercion. In Downs v. Wortman, 228 Ga. 315, 185 S.E. 2d 387 (1971), the court determined that an offer of plane fare to a mother in exchange for consent to the adoption of her child, was a contract void as against public policy since the mother's consent could not have been freely and voluntarily given. But if this were taken as a standard in the surrogate mother situation, any payment to the surrogate might be sufficient to void her consent.
58. See Lori B. Andrews, "Ethical Considerations in In Vitro Fertilization and Embryo Transfer" 403, 412-413, in Wolf and Quigley, supra n. 19 for examples of potential coercion, such as high fees and undue influence by a family member or employer.
59. Colo. Rev. Stat. §19-6-106 (1) (1978); Conn. Gen. Stat. §45-69h (1981); Kan. Stat. Ann. §23-130 (1981); Minn. Stat. Ann. §257.56 subdiv.1. (1982); Mont. Rev. Code Ann. §40-6-106(1) (1981); Nev. Rev. Stat. §126.06(1) (1979); Okla. Stat. Ann. tit. 10 §553 (West Supp. 1982-83); Or. Rev. Stat. §109.239(1) (1981); Wash. Rev. Code Ann. §26.26.050(1) (West Supp. 1983-84); Wis. Stat. Ann. §891.40(1) (West Supp. 1983-84); and Wyo. Stat. §14-2-104(1) (1978).
60. Ernest Roland P., Jr. v. Superior Court of Orange County, 49 U.S.L.W. 2350 (1980).
61. Michelle W. v Ronald W., 139 Cal. App. 3d 24, 188 Cal. Rptr. 413, 417 (1983). See also, A v. X, Y, & Z, 641 P. 2d 1222, 1225 (Wyo. 1982).

62. Contrast this to the situation in which the husband of a married woman is presumed to be the father of her child. Recognizing the paternity of the child to belong to another man could disrupt the woman's family relationship since it is unlikely that her husband agreed to her impregnation by another man to create a child.
63. Nevertheless, legislators may feel more comfortable if they maintain some tie to the biological approach to paternity by enacting laws allowing the intent approach to govern only in situations where one or the other spouse has a biological link to the child. Such a law would allow surrogate motherhood (since the husband is the genetic father), artificial insemination (since the wife is the genetic and gestational mother), embryo transfer or embryo adoption (since the wife is the gestational mother) or the use of a surrogate carrier in instances where one or both of the societal parents is a genetic parent. The law could draw the line and not recognize the use of a surrogate mother inseminated with donor sperm or the use of a surrogate carrier to gestate an embryo unrelated to the couple who will be raising the child. In this way, the biological link of the child to at least one of the people who would be raising him or her would lend support for the non-involvement of adoption officials. Since there would be a biological reason that the individual should be recognized as the parent of the child, the situation is distinguishable from that of adoption where officials need to choose between competing potential parents, none of whom are biologically linked to the child.
64. The logic of Roe v Wade, 410 U.S. 113 (1973), would seem to apply.
65. Although some surrogates who wish to abort may be deterred from doing so because they feel they cannot afford to return the money, this requirement would seem to be no more a burden on their right to abort than is the lack of payment for abortions from private funds (which was held constitutional in Maher v. Roe, 432

U.S. 464 (1977)). Typically, the amount the surrogate would have to return would be greater than the amount an abortion was estimated to cost in Maher, but, since payment to a surrogate is usually structured, with the bulk received held in escrow until after the child's birth and/or adoption by the couple, the amount will not generally be more than around \$2000.

66. Protection of the child for tort law purposes begins at conception if the child is born alive. Mark I. Evans and Alan O. Dixler, "Human In Vitro Fertilization: Some Legal Issues," 245 Journal of the American Medical Association 2324 (1981).
67. Rich women typically do not become surrogates. Phillip Parker, "Motivations of Surrogate Mothers: Initial Findings," 140 Am. J. Psychiatry 117 (Jan. 1983).
68. By allowing lawsuits based on actual harm to the child, an attempt can be made to deter injurious behavior without subjecting a woman to medical whim by restricting her behavior in situations which may or may not cause harm to the fetus. One might suggest that the empirical medical research is sufficient to enable advance predictions of which pregnancy behaviors will be harmful, but studies of risk to the fetus are not universally well designed or illuminating. For example, some studies claim to show that paid work during pregnancy is harmful to the child, while others purport to have just the opposite finding. See Geoffrey Chamberlain and Jo Garcia, "Pregnant Women at Work," The Lancet 228 (January 29, 1983).

69. Substitute for Michigan House Bill 4114, Draft 2, as amended.
70. Letter, Laurene Masecla, Bryan York Colwell, Janet A. Couch, "Should Sperm Donors Be Screened For Sexually Transmitted Diseases?" 309 New England Journal of Medicine 1058 (1983).
71. See Johnson, et al., supra. n. 43 and Shapiro and Hutchinson, supra. n. 43.
72. The American Fertility Society, Report of the Ad Hoc Committee On Artificial Insemination (1980).
73. "Reproductive Council Guidelines," 4 American Association of Tissue Banks Newsletter (Supp.) 38-40 (1980).
74. Id. at 38.
75. Curie-Cohen et. al., supra n. 42 at 588. Although this survey was published five years ago, in a recent interview, one of the original researchers pointed out the practices had not changed much since then. Andrews, supra n. 8 at 56.
76. Curie-Cohen, et. al., supra. n. 42 at 588.
77. Mark S. Frankel, "Artificial Insemination and Semen Cryobanking: Health and Safety Concerns and the Role of Professional Standards, Law and Public Policy," 3 Legal Medical Quarterly 93, 94 (1979) indicates that this is not routinely done.

78. City of New York Health Code §§21.03, 21.05.
79. Or. Rev. Stat. §677.370 (1981).
80. Washington, D.C. Council Bill, "Sperm Bank Licensure Act of 1983," introduced by Council member John Ray.
81. Mark E. Cohen, "The 'Brave New Baby' and the Law: Fashioning Remedies for the Victims of In Vitro Fertilization," 4 American Journal of Law and Medicine, 319, 334 (1978), suggests that practitioners of in vitro fertilization be held strictly liable for harm to the child.
82. Federation CECOS, J. F. Mattei, and B. Le Marec, "Genetic Aspects of Artificial Insemination by Donor (AID). Indications, Surveillance, and Results," 23 Clinical Genetics 132 (1983).
83. John D. Biggers, "In Vitro Fertilization and Embryo Transfer In Human Beings," 304 New England Journal of Medicine 336, 341 (1981).
84. T. J. Williams, R. P. Elsdon, and G. E. Seidel, Jr., "Identical Twin Bovine Pregnancies Derived From Bisected Embryos," 17 Theriogenology: An International Journal of Animal Reproduction 114 (1982).
85. This assumes a 50% success rate for artificial insemination by donor, which is much lower than the reported rate. A study of 2,193 French women undergoing artificial insemination by donor with sperm that had been frozen found that 73 percent of the women under age twenty-five conceived, as did 74.1 percent of the twenty-

five to thirty age group, 61.5 percent of the thirty-one to thirty-five age group, and 53.6 percent of the women over age thirty-five. See Federation CECOS, D. Schwartz and M. J. Mayaux, "Female Fecundity as a Function of Age: the Results in 2193 Nulliparous Women with Azoospermic Husbands," 306 New England Journal of Medicine 404 (1982) and Alan H. DeCherney and Gertrude Berkowitz, "Female Fecundity and Age," 306 New England Journal of Medicine 424 (1982). The earlier Curie-Cohen et al. study, supra, n. 42 at 588, found an overall 57% success rate for artificial insemination with fresh sperm in the United States.

86. Curie-Cohen, et al., supra, n. 42 at 587.
87. Royal College of Obstetricians and Gynaecologists, Report of the RCOG Ethics Committee on In Vitro Fertilisation and Embryo Replacement or Transfer (Chameleon Press, London, 1983).
88. See "The Emotions of Infertility and Medical Genetics", and "Parenting and the New Conceptions," in Lori B. Andrews, New Conceptions: A Consumer's Guide to the Newest Infertility Treatments Including In Vitro Fertilization, Artificial Insemination and Surrogate Motherhood (New York, St. Martin's Press, 1984). The use of these procedures also has psychological ramifications for the scientists and clinicians involved. Indeed, Kass has suggested the need for concern for the effect that in vitro fertilization and the extracorporeal embryo might have on practitioners' "attitude toward and respect for human life." Leon P. Kass, "Making Babies — the New Biology and the 'Old' Morality," 26 Public Interest 18, 33 (1972).

89. Andrews, supra, n. 88 at 223.
90. Id. at 278-9.
91. The attempt to preserve secrecy may be burdensome to the couple. Christine Manuel, Marie Chevrete and Jean-Claude Czyba, "Handling of Secrecy by AID Couples," 419, 421, in G. David and W. S. Price, eds., Human Artificial Insemination and Semen Preservation (New York, Plenum Press, 1980). This discomfort may be conveyed to the child, causing him or her to feel awkward.
92. Some children are informed in a punitive way that they were conceived through artificial insemination and this may harm their self-esteem. See Andrews, supra, n. 88 at 276-7.
93. See Lori B. Andrews, "The Stork Market", Savvy 12 June 1984.
94. Infertility (Medical Procedures) Bill 1984 proposed by Hon. J. H. Kennan, 20 March 1984.
95. Tricia Crane, "New Strategies in the Adoption Game," Los Angeles Herald Examiner E 1, 11 (February 26, 1984).
96. The organizations are the International Soundex Reunion Registry, Post Office Box 2312, Carson City, Nevada 89701 and Donors Offspring, Post Office Box 33, Sarcoux, Missouri 64862.

97. Maheer v. Roe, 432 U.S. 464 (1977).
98. This situation will be less likely to occur once parental rights and responsibilities are clarified by the types of laws suggested supra. at n. 57-63.
99. Andrews, "Ethical Considerations in In Vitro Fertilization and Embryo Transfer," supra. n. 58 at 418-419.
100. P. Handler, Biology and the Future of Man 926 (Oxford University Press, New York, 1970).
101. Joseph Fletcher, "Ethical Aspects of Genetic Controls," 285 New England Journal of Medicine 776, 779 (1971).
102. R. G. Edwards, "Fertilization of Human Eggs In Vitro: Morals, Ethics and the Law," 49 Quarterly Review of Biology, 3, 15 (1974).
103. Medical Research Council, "Research Related to Human Fertilisation and Embryology," 285 British Medical Journal 1480 (1982)
104. Pennsylvania has taken a limited step in that direction with an in vitro law that attempts to monitor the results of the procedure by providing that anyone conducting in vitro fertilization must file quarterly reports with the Department of Health describing the names of everyone conducting or assisting in the process, the locations where the fertilization takes place, names and addresses of the

individuals or institutions sponsoring the procedures, the number of eggs fertilized, the number of embryos destroyed or discarded and the number of women implanted with embryos. The names of the donors or recipients of the gametes are not required. Pa. Stat. Ann. tit. 18 §3213(e) (Supp. 1983-4).

105. In fact, the federal regulations governing institutional review boards considering proposals for federally funded research explicitly state "The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility." 45 C.F.R. §46.111(a) (2) (1984). While these regulations have no legal application to research on alternative reproduction that is not federally funded, institutional review boards are generally influenced by the federal guidelines with respect to all research proposals they review.

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Lori Andrews' publications on the new reproduction technologies include New Conceptions: A Consumers Guide to the Newest Infertility Treatments Including In Vitro Fertilization, Artificial Insemination and Surrogate Motherhood (1984); "The Stork Market: The Law of the New Reproduction Technologies," 70 American Bar Association Journal 50 (1984); "Legal Issues Raised by In Vitro Fertilization" and "Ethical Considerations in In Vitro Fertilization" in Don P. Wolf and Martin M. Quigley, eds., Human In Vitro Fertilization and Embryo Transfer (1984); and "Removing the Stigma of Surrogate Motherhood," 4 Family Advocate 20 (No. 2, 1981). Other recent publications include "Informed Consent Statutes and the Decisionmaking Process," 5 Journal of Legal Medicine 165 (1984); Deregulating Doctoring (1984); "The Model Rules and Advertising," 68 American Bar Association Journal 808 (1982), The Rights of Fair Trial and Free Press—The ABA Standards (1981); Birth of a Salesman: Lawyer Advertising and Solicitation (rev. ed. 1981); and "Lawyer Advertising and the First Amendment," 1981 American Bar Foundation Research Journal 967.

Lori Andrews' speeches to professional organizations include "The New Reproduction Technologies and the Law," American Bar Association Annual Meeting, Chicago, August 1984; "Consumer Evaluation in Health Care," Association of Health Care Quality Annual Meeting, Chicago, June 1984; "Lay Participation in Health Care in the United States," World Health Organization Working Group on Lay Participation in Health Care, Dubrovnik, Yugoslavia, November 1983; "Whose Child Is It Anyway? Legal Regulation of Medically-Assisted Means of Procreation," Clinical Seminar, American Fertility Society Annual Meeting, San Francisco, April 1983; "Legal and Ethical Aspects of Reproduction," University of Texas Continuing Medical Education Seminar, Houston, November 1982; "Surrogate Mothers and the Law," World Conference on Embryo Transfer, In Vitro Fertilization, and Instrumental Insemination, Kiel, West Germany, September 1980.

Lori Andrews is an advisor to the World Health Organization Regional Office for Europe and serves on the Board of Directors of a 60,000 member nonprofit organization for health care consumers, the Peoples Medical Society. She won a Maggie Award from Planned Parenthood in 1983 for her article, "Genetic Counselors: How They Can Help and How They Cannot."

Mr. DURBIN. Thank you very much, Ms. Andrews.

Our final witness on this panel is Prof. George Annas, Uteley professor of health law, Boston University School of Public Health. Welcome.

Mr. ANNAS. Thank you, Congressman Durbin.

My colleagues have raised a lot of issues today, and I certainly don't want to repeat anything they've said, so instead of reviewing them, what I'd like to do is concentrate on two specific issues and try to give some answers—to those two issues at least.

It seems to me that the new technologies that Lori Andrews just talked about close the circle that we opened about 20 years ago with birth-control technology that made possible, for the first time, sex without reproduction. Our new technologies now make possible reproduction without sex. And the societal implications of those are likely to be at least as great, as those with the advent of effective birth-control methods.

The three countries that now engage in a considerable amount of use of these technologies have different words for it. And I was intrigued by Alex Capron's vocabulary as he, I think, will be by realizing that, in Australia, these techniques are called abnormal reproduction. In England, they're called unnatural methods of reproduction. And here in the United States they're called artificial methods of reproduction. They're all the same methods, but the language the countries use are considerably different. And they may or may not—I—a mere—the way the various populations and commentators at least feel about them.

Today, though, rather than get involved in that, that level of theoretical debate, let me concentrate on two specific issues.

The first one is a traditional issue, one that's always been a question in family law, and is just given a new wrinkle in the new technologies—that is, who should be considered the legal mother and who should be considered the legal father in these cases.

And the second, using Alex's division, is to look at the protections that the law ought to afford the extracorporeal embryo.

Let me begin first with the question of identifying the mother and the father.

Artificial insemination by donor, for the first time, separated the genetic mother—genetic father, I'm sorry—of the child from the act of sexual intercourse in its conception.

The procedure—artificial insemination by donor—has become recognized as a standard treatment modality for infertility of a married couple due to male sterility. It has also become customary to use the sperm of an anonymous donor, and so long as the husband of the woman consents, the anonymous donor is not considered the legal father of the child.

Thus, we have developed a technique in which the genetic father has been replaced by the mother's husband as a legal father of the child.

This model places personal agreements or contracts among the parties ahead of genetic or bloodline considerations; and this contract model has been suggested as the one we should apply to embryo transfer. The question is whether or not it fits.

Actually, the reason we require legislation in the 25 States that have it to say that the sperm donor shall not be considered the

legal father of the child, is that we've always considered the genetic father to be a legal father, and the social father.

Nonetheless, to protect the children and foster families, children born during the course of any marriage are legally presumed to be legitimate offspring of the couple. This is probably a reasonable rule because it protects the child and helps ensure that it has at least one other parent, in addition to its mother, who is identifiable as financially responsible for its well-being, and who is likely to be there to help rear the child.

But in dealing with the mother, however, we have additional biological considerations that make the identification issue more complicated. In males, we need only distinguish between the genetic and the rearing father.

As John Robertson has noted, in females we might have to distinguish between the genetic mother and the gestational mother, and distinguish both of them from the rearing mother.

And the question is, which of these three, when they are different women, should the law presume to be the legal mother of the child, and that is the woman who has the obligation to support and nurture the child?

This is a completely novel question. Previously, at birth there was never any question as to who the mother was since she was always both the genetic and gestational mother; the only identity question regarded the father.

But now in cases of surrogate embryo transfer, which will be discussed tomorrow, an embryo transfer to a woman other than the egg donor, the identity of the genetic and gestational mother will be different.

So which of these two women should the law identify as the legal mother?

I believe that it's between the genetic and gestational mother, the current legal presumption that the gestational, or birth mother, is the legal mother should remain. This gives the child and society certainty of identification at the time of birth, which is a protection for both the child and the mother; and also recognizes the biological fact that the gestational mother has contributed more of herself to the child than the genetic mother and, therefore, has a greater biological investment and interest in it, and probably a greater psychological bond to it.

The consequences of this is, are that if any agreements regarding transfer, relinquishing of parental rights, or adoption ought to be made, they should be made only by the gestational mother, and only after she has had a reasonable time after the birth to consider all of her and her child's options.

In summary, regarding paternity, to protect both the integrity of the family and the interests of the child involved, the current legal assumptions, I believe, should remain; and they are that the child's father should be presumed to be the husband of the child's mother, and the child's mother should be presumed to be the woman who gave birth to the child.

We can permit the husband to overcome the presumption of paternity by presenting proof beyond a reasonable doubt in court; but I believe the maternal presumption should be conclusive and irre-

butable, or, again, certainty of identification and protection of both mother and child.

The second issue I'd like to address briefly is protection of the extracorporeal embryo. Whether and how we should protect extracorporeal embryos at all depends on how we view them, of course. We need not consider them to be either a person to afford them legal protection, legally recognized protection, anymore than we consider a dog a person to protect it against cruelty; or a dolphin a person to protect it against destruction; or a national park a person to protect it against loggers. Nor need we grant the embryo any legal rights of its own to afford it legal recognition.

Other witnesses have discussed, and will discuss, issues involving research. And in an appendix I have submitted with my testimony, I discuss the issue of patenting.

Today, I'd like to concentrate orally on the issue that I believe has not received much attention—with the exception of Professor Robertson's testimony—the protection and sale of frozen embryos.

The embryo, the human embryo, I believe, is equal to more than the sum of its constituent parts. It not only has the complete genetic complement of a human being, but is also a powerful symbol of human regeneration. We can thus value it and afford it legal recognition even though we do not value or legally recognize either the egg or the sperm.

On the other hand, we do recognize and accept the significant loss of embryos in nature, and we make no efforts to recover and freeze them. We also do permit the destruction of, and research on, fetuses under certain circumstances.

Thus, what we seem to be dealing with here are the added obligations that we incur by actively intervening in the natural process of human reproduction by using freezing techniques as a method of embryo storage.

To protect the gamete donors, and the interests of society in protecting the integrity of assisted reproduction techniques, I believe embryos should only be frozen with the informed consent of both gamete donors, and only for a specific and specified purpose; usually that purpose will be used in subsequent cycles when a pregnancy is not obtained in the first cycle in IVF.

When the purpose is fulfilled—that is, a pregnancy is obtained—the embryo should be destroyed. Likewise, when something other than the original use of the embryo is contemplated, the informed consent of both gamete contributors should be required.

If only one is alive, that one should have the decisionmaking authority, since that person has the most interest in and is thus most likely to be protective of the embryo. When they both die, I believe the embryo should be destroyed.

Recommendations like those of the Warnock Commission to permit the frozen embryo to pass to the storage facility to be disposed of as it sees fit when both gamete donors die, treat the embryo too much like a commercial product, and give insufficient weight to its origins and its symbolic value.

A final issue I'd like to address briefly is that of sale of frozen embryos. I think John Robertson correctly points out, that we need more than moral revulsion to constitutionally legislate and prohibit the sale of frozen embryos, or embryos at all in this country.

This committee held hearings last November, at which there was almost a universal consensus that kidneys should not be bought or sold in this country. I agreed with that position, and so testified before this committee.

The arguments against the sale of human embryos are more compelling, although different. There's not the specter here of a coercive offer that exploits the bodies of the poor, as it was with kidney sales. But this is replaced, I believe, by the potential of a commercial market in prefabricated, selected embryos, and encourages us to view embryos as things or commodities which are simply means to whatever ends we design, rather than as human entities without a market price.

Ian Kennedy has argued that we know intuitively that a human embryo is more valuable than a hamster or other experimental animal, and that is why we have trouble permitting experiments on human embryos.

Likewise, we know intuitively that a human embryo is more valuable than a kidney and of much more symbolic importance regarding human life; and that is why we feel that human embryos should not be the subject of commerce.

The reason is not so much the embryo itself, although many will find its intrinsic value sufficient justification to outlaw sales, but the implications for the children that will result following the sale and implantation of a frozen embryo.

Specifically, embryos will be bought and sold, if at all, on the basis that they will produce a healthy child, and possibly that they will produce a healthy child of a certain type, IQ, stature, color, et cetera.

When the child is not born as warrantied or guaranteed, the issue will be what remedies the buyer has against the seller.

Even a brief glance at the sales provisions of the Uniform Commercial Code, which will be the statute under which such sales will be permitted, if at all, in this country, suggests that we either must outlaw sales or write a new statute which would cover embryos.

The Uniform Commercial Code, for example, provides that "if the goods or the tender of delivery fail in any respect to conform to the contract, the buyer may reject the whole; accept the whole; or accept any commercial unit or units and reject the rest."

This may be read—the latter provision may be read as applying to twins or triplets, I take it; and the first section leaves us wondering who is responsible for the child if the buyer rejects the whole shipment. Likewise, a section of the Code state that, "if the seller gives no instructions within a reasonable time after notification of rejection, the buyer may store the rejected goods for the seller's account, may reship them to him, or resell them for the seller's account." This, of course, could be read as applying directly to the frozen embryo itself, but its potential application to the child produced as a result of the embryo transfer process simply illustrates the inappropriateness of sales in this area at all, and the ease with which the sale of human embryos can quickly become confused with the sale of human children.

In conclusion and summary then, I would argue that we have to be very cautious in this area. On the other hand, we're dealing with some old problems and some new problems, which is the

reason, I think, that any universal solution is not likely to be terribly effective.

I agree with those speakers who have called for additional work by professional associations and organizations in an attempt to develop guidelines. It is obviously not appropriate for one individual specialty to develop guidelines and expect that they—those to be recognized by all other specialties.

It's no more likely, for example, that the American Fertility Society would accept recommendations by this legal panel as to how they should perform the medical aspects of in vitro fertilization and surrogate embryo transfer than that this legal panel or the ethical panel tomorrow is likely to accept the ethical precepts dictated by the American Fertility Society.

We obviously need multidisciplinary input in the development of guidelines, but it seems to me that the professional organizations have made a major start on this; and that one very worthwhile thing would be for professional organizations, with public input, to try to get together and agree on some guidelines as to how these procedures should be done in the clinics.

Second, on the State level, I agree with those who have proposed the model State law. Just because we can't answer all the questions, and we can't, doesn't mean we shouldn't start answering the ones we can answer. And specifically, I think it's important that a model law be developed which sets out the identity of the mother and the father for the protection of both child and parents; and also has specific provisions for recordkeeping and record retention.

Thirdly, I'm not a great fan of commissions, as many of the other people are here. On the other hand, certainly, there can be little objection to a commission, and it can—probably can't do any harm, and may, indeed, do some good. So that if there was a—some feeling on the Federal level that a commission would be appropriate, it would be hard to object to that. On the other hand, I—I would not like to see the fact that there was a proposed commission on the horizon used as an excuse by individuals not to try to develop guidelines; not to get some reasonable State laws in place; and to postpone action until the day which continues to come, that we are again overcome and overwhelmed by the science, and unable to do anything but react to it.

Thank you.

[The prepared statement of Mr. Annas follows:]

TESTIMONY

by

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LEGAL ASPECTS OF HUMAN EMBRYO TRANSFER

Mr. Chairman and members of the Subcommittee, thank you for inviting me to address the legal aspects of human embryo transfer. As past Chairman of the Committee on Science and the Family of the American Bar Association's Family Law Section from 1980 to 1982, and as current Chairman of the Committee on Legal Problems in Medicine of the ABA's Science and Technology Section I have been thinking about the legal implications of new non-coital human reproduction techniques for a number of years. In focusing on human embryo transfer, you have correctly identified the area that presents the most complexities and has raised the most concern. The genie is out of the lamp, and cannot be put back in. But we still have the opportunity and obligation to use our new techniques in a manner consistent with our strongly held values regarding the pricelessness of human life, and the primacy of the family in our society.

My views on Embryo Transfer are well summarized in an article which I recently co-authored with Dr. Sherman Elias of Northwestern U. Medical School, In Vitro Fertilization and Embryo Transfer: Medicolegal Aspects of a New Technique to Create a Family, which I would like to incorporate into my testimony as Appendix I to this prepared statement. Rather than simply restate the text of the article, however, I would like to concentrate my comments today on two specific aspects of Embryo Transfer: (1) the implications for identification of the resulting child's mother and father; and (2) the protections the law ought to afford the extracorporeal embryo.

I. IDENTIFICATION OF THE MOTHER AND FATHER

Artificial insemination by donor (AID) for the first time separated the genetic father of a child from the act of sexual intercourse in its conception. The procedure has become recognized as a standard "treatment" modality for infertility of a married couple due to male sterility. It has also become customary to use the sperm of an anonymous donor who (so long as the husband of the woman consents) is not considered the legal father of the child. Thus we have developed a technique in which the genetic father is replaced by the mother's husband as the legal father of the child. This model places personal agreements or contracts among the parties ahead of genetic or "blood line" considerations, and has been suggested as the model to apply to embryo transfer. The question is whether it fits. The Warnock Commission, for example, recommended that

In order to achieve some certainty in this situation [egg donation]...legislation should provide that when a child is born to a woman following donation of another's egg the woman giving birth should, for all purposes, be regarded in law as the mother of that child, and that the egg donor should have no rights of obligations in respect of the child.

This treats the donation of sperm and egg on an equal footing and seems reasonable as far as it goes; but it does not go far enough. The reason we require legislation to guarantee the obligations of the social or rearing father and extinguish the rights and obligations of the genetic father is that society has always assumed that the genetic father is the father of the child for all purposes.

Nonetheless, to protect children and foster families, children born during the course of a marriage are legally presumed to be the legitimate offspring of the couple. In most states the husband must affirmatively disown the child and present evidence in court proving beyond a reasonable doubt that he is not the genetic father to successfully challenge this legal presumption. This is a reasonable rule because it protects the child and helps insure that it has another parent (in addition to its mother) who is identifiable as financially responsible for its wellbeing, and who is likely to be there to help rear the child.

In dealing with the mother, however, an additional biological consideration makes the identification issue more complicated. In males one need only distinguish the genetic from the social or rearing father. But, as John Robertson has noted, in females we might now have to distinguish the genetic mother from the gestational mother from the rearing mother. The question is, of these three (when they are different women), which one should the law presume is the legal mother and thus has the obligation to support and nurture the child?.....

This is a completely novel question. Previously, at birth there was never any question who the mother was since she was always both the genetic and the gestational mother (only the identity of the father was uncertain, and this uncertainty was clarified by a social decision to presume paternity in the mother's husband). Now, in cases

of surrogate embryo transfer, and embryo transfer to a woman other than the egg donor, the identity of the genetic and gestational mother will be different. The question is, which of these two women has a greater claim to be identified in law as the child's "mother", and is her claim superior to any claim a rearing mother might have who is neither genetically nor gestationally connected to the child?

I believe that as between the genetic and gestational mother, the current legal presumption that the gestational (or birth) mother is the legal mother should remain. This gives the child and society certainty of identification at the time of birth (a protection for both mother and child), and also recognizes the biological fact that the gestational mother has contributed more of herself to the child than the genetic mother, and therefore has a greater biological investment and interest in it. If any agreements regarding transfer, relinquishing of parental rights, or adoption are to be made, they should be made only by the gestational mother, and only after she has had a reasonable time after the birth to consider all her and her child's options.

In summary, to protect both the integrity of the family and the interests of the children involved, the current legal presumptions should remain: the child's father should be presumed to be the husband of the child's mother, and the child's mother should be presumed to be the woman who gave birth to the child. We can permit the husband to overcome this presumption by presenting proof of

nonpaternity beyond a reasonable doubt (so long as he did not consent to the procedure which resulted in the birth), but the maternal presumption should be conclusive and irrebutable for certainty of identification and the protection of both mother and child.

II. PROTECTION OF THE EXTRACORPOREAL EMBRYO

Whether and how we should protect the extracorporeal embryo depends upon how we view it. We need not, of course, consider it a person to afford it legally recognized protection, any more than we need consider a dog a person to protect it against cruelty, or a dolphin a person to protect it against destruction, or a national park a person to protect it against loggers. Nor need we grant the embryo any legal rights of its own to afford it legal recognition.

With in vitro fertilization (IVF) in which all fertilized eggs are replaced in the uterus of the ovum donor (embryo replacement) the issue of embryo protection concerns mainly care of it for the short time it is in vitro. Protection becomes a much more important issue if some of the embryos are not replaced, and are instead either used for research or frozen for use (either for future implantation or research). The issue of research on the embryo is being dealt with by others at this hearing, and has been addressed by the Ethics Advisory Board and other groups. No satisfactory guidelines have yet been found, but most seem to agree that no research should be conducted on the embryo without the informed consent to both gamete contributors,

and the prior approval of the experiment by an Institutional Review Board which finds the proposed research important. Most commentators and commissions have also recommended a time limit on growing embryos, with 14 days now seen as the maximum (see, e.g., recommendations of Warnock Commission). The jury is still out on this, and the ethicists who will speak to you tomorrow will undoubtedly focus on this issue.

Another issue, which I have written on elsewhere, involves patenting the process to produce the embryos. My current inclination is to oppose such patent applications, and my reasons for this are set forth in Appendix B, SET: The Perils of Patenting; to this testimony. I'd like to concentrate my testimony today on two related issues that have not received much attention: the protection and sale of frozen embryos.

A. Protecting Frozen Embryos

The human embryo is equal to more than the sum of its constituent parts. It not only has the complete genetic complement of a human being, but it also is a powerful symbol of human regeneration. We can thus value it and afford it legal recognition even though we do not so value or legally recognize either the egg or the sperm. On the other hand, we do recognize and accept a significant loss of embryos in nature, and make no efforts to recover and freeze them. We also permit destruction of and research on fetuses under certain circumstances. Thus what we seem to be dealing with here are the added obligations that we incur by actively intervening in the natural

process of human reproduction by using freezing techniques as a method of embryo storage.

To protect the gamete donors, and the interests of society in protecting the integrity of assisted reproduction techniques, embryos should only be frozen with the informed consent of both gamete donors, and only for a specific and specified purpose (usually use in subsequent cycles when a pregnancy is not obtained). When the purpose is fulfilled (e.g., a pregnancy obtained) the embryo should be destroyed. Likewise, when something other than the original use of the embryo is contemplated, the informed consent of both gamete contributors should be required. If only one is alive, that one should have the decision-making authority, since that person has the most interest in and is thus likely to be most protective of the embryo. When they both die, the embryo should be destroyed. Recommendations like that of the Warnock Commission to permit the frozen embryo to pass to the storage facility to dispose of as it sees fit (subject to certain licensing laws) treat the embryo too much like a commercial product, and give insufficient weight to its origins and symbolic value.

B. Sales of Frozen Embryos

This Committee held hearings last November at which there was an almost universal consensus that kidneys should not be bought and sold in this country. I agreed with that position and so testified before

this Committee. The arguments against the sale of human embryos are even more compelling. Although there is not the spectre of a coercive offer that exploits the bodies of the poor, this is replaced by the potential of a commercial market in prefabricated, selected embryos, that encourages us to view embryos as things or commodities which are simply means to whatever ends we design, rather than as human entities without a market price. Ian Kennedy has argued that we know intuitively that a human embryo is more valuable than a hamster or other experimental animal, and that is why we have trouble permitting experiments on human embryos. Likewise, we know intuitively that a human embryo is more "valuable" than a kidney and of much more symbolic importance regarding human life: that is why we feel that embryos should not be the subject of commerce. The reason is not so much the embryo itself (although many will find its intrinsic value sufficient justification to outlaw sales), but the implications for the children that will result following the sale and implantation of a frozen embryo.

Embryos will be bought and sold, if at all, on the basis that they will produce a healthy child-and possibly that they will produce a healthy child of a certain type, IQ, stature, etc. When the child is not born as warrantied or guaranteed, the issue will be what remedies the buyer has against the seller. Even a brief glance at the Sales provisions in the Uniform Commercial Code (UCC) informs us that this is not an area that we can permit sales in (or if we do permit sales in it, it is an area we need a new set of sales statutes to

control). The UOC provides, for example, that "if the goods or the tender of delivery fail in any respect to conform to the contract, the buyer may (a) reject the whole; or (b) accept the whole; or (c) accept any commercial unit or units and reject the rest." (sec. 2-601)

Section (c) might be read to apply to twins or triplets, and section (a) leaves us wondering who is responsible for the child. Likewise, "if the seller gives no instructions within a reasonable time after notification of rejection the buyer may store the rejected goods for the seller's account or reship them to him or resell them for the seller's account..." (sec. 2-604) This could be read as applying more directly to the frozen embryo itself, but its potential application to the child produced as a result of the embryo transfer process simply illustrates the inappropriateness of sales in this area at all, and the ease with which sale of human embryos can quickly become confused with sale of human children. In this regard the Warnock Commission is correct in recommending legislation to ensure "there is no right of ownership in a human embryo."

Conclusion

The lessor of Aladdin is not only that we must be cautious with genies, but also that we should not exchange "new lamps for old" until we know the value of each. It would be most desirable to have the state and federal government stay out of the arena of human reproduction. Unfortunately, if the children resulting from new techniques such as surrogate embryo transfer and the use of frozen

embryos are to be sufficiently protected, this is no longer possible. Private contractual agreements generally favor the interests of the infertile couple over those of the potential child—to the latter's potential detriment. Nonetheless, premature and ill-considered legislation could do more harm than good.

Accordingly, professional organizations in the area of human reproduction should work with organizations devoted to protecting civil liberties and the interests of children to design detailed guidelines that can serve as standards for the medical profession, and model legislation that can be enacted by the individual states to protect the interests of parents and their children. The American Bar Association's Committee on Legal Problems in Medicine stands willing to lend its help and cooperation to such an effort. Your committee is to be commended for holding these hearings and encouraging both public and professional dialog on these important issues, and I appreciate the opportunity to participate.

Mr. DURBIN. Thank you very much, professor, and I want to thank the panel.

We are going to recess for a few minutes here again—I'm called to a rollcall, ironically, for the Legal Services Corporation.

I have a list of questions here I'm anxious to ask you, and I hope I have an opportunity to return. If we could stand in recess for a few minutes, Chairman Gore will be returning, and perhaps 10 minutes—10 minutes, and we'll get back to the panel. Thank you.

[Recess.]

Mr. GORE [presiding]. The subcommittee will come back to order. If all of our witnesses could rejoin us, I will defer to Mr. Durbin when he gets back here from voting. But let me begin with several questions here.

Mr. Annas, in your testimony, one of the things you said is that you would recommend outlawing the sale of human embryos; correct?

Mr. ANNAS. That is correct, yes.

Mr. GORE. Does anyone on this panel disagree with that recommendation?

Mr. ROBERTSON. Well, I—do, at least I would like to raise some reservations about it before we proceed ahead—and do that, and

point out that just as we sell sperm, it—as a way of making gametes available to a couple that lacks them, it may be the only way that embryos may become available to an infertile married couple. And perhaps for that reason, it should be possible to pay money for them.

After all, if the couple could buy sperm separately, and then buy the eggs separately, doesn't matter that much that you bought them separately, then combined them yourself, or you—or you bought them and someone else has combined them.

And the case I'm thinking of—is one where there's excess embryos. The couple that provided them doesn't want the embryo anymore and would destroy it unless someone is willing to pay them not to; that would protect the embryo from being destroyed, and it would fulfill the needs of the others. So—

Mr. GORE. Well, I think I disagree with you on that, for what that's worth.

Mr. ROBERTSON. Sure.

Mr. GORE. We had hearings on the sale of human organs, and—

Mr. ROBERTSON. I'm aware of that.

Mr. GORE [continuing]. You may have disagreed with that as well.

Mr. ROBERTSON. Well—

Ms. ANDREWS. I think the human organ situation does not present the same constitutional question of implicating a right to procreate, and I think that's what Professor Robertson was getting at.

Mr. GORE. Uh-huh.

Ms. ANDREWS. So we need to go another step and say what sort of harm are we trying to protect against. And one of the harms that was brought up was that perhaps people will expect more of their children. It's like buying a Mercedes instead of a VW if you paid for the embryo. And yet—I mean, I think the evidence is that this is one of the lesser costs in the whole treatment of infertility, that doctor's fees are very high, the investigations. Right now, caesarean sections cost twice as much as a normal childbirth; yet, we don't expect twice as much of those children.

So I think that between the constitutional constraints and the fact that payment for infertility service is very common, some of the potential harms have been blown out of proportion.

Mr. GORE. Yes.

Mr. CAPRON. Mr. Chairman, I think it would be ironic if we were to have a situation in which a—we were to say that a person has fewer rights under the Constitution to protect their own life by obtaining a lifesaving organ than they have to procreate any which way they wish, when another person's life—the future life of that child to be, or in the case of an embryo, treating it as a piece of commerce is involved.

And I guess I do disagree with Professor Robertson's reading of these procreative freedom cases. It's ironic that most all those cases in fact deal with situations in which the court was upholding people's rights not to have children. And he has written extensively—I don't find persuasively, although I do find eloquently, and very learnedly—

Mr. GORE. You guys—you guys treat each other the way we treat each other up here, and——

[Laughter.]

Mr. CAPRON. My learned colleague from the University of Texas, who has slipped into error on this, but——

[Laughter.]

Mr. CAPRON [continuing]. It seems ironic to me that in his testimony he told us that *Roe v. Wade* and the other cases apparently create a right that would allow procreation, but they would not allow destruction of the embryos. He said they might not go that far. And yet, ironically, those cases indeed do deal with the destruction of fetuses.

His argument that because we now have commerce in sperm, and I guess in eggs, too, we must, therefore, it follows logically that we would have commerce in embryos, and that that would be equally protected I think, misunderstands something about the difference between the constituent parts of a embryo—that is to say, the sperm and egg that go into making it up—not just, I believe, in some arcane legal sense, but in most people's deeply felt philosophical sense——

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. That there is something different in most religious and ethical traditions between the egg and sperm before they're united and after they're united. And I would suggest——

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. That, for example, most people would feel more comfortable making restrictions on fetal research than on sperm research.

Mr. GORE. Well, let me give you a chance to respond, Professor Robertson, but beforehand let me—let me inject another hypothetical into the mix, and that is again in the area of transplantation. Doctors in Sweden have now demonstrated the ability to successfully treat Parkinson's disease by transplanting fetal brain tissue into the brain of the adult with something like a, I don't know, maybe a 25-percent success rate, which is a lot better than zero, which I think it has been before.

And at that point, commerce in embryos would be very similar to commerce in—transplantable organs. But—go ahead.

Mr. ROBERTSON. Well, with all respect to the position your committee took earlier in the legislation you recommended on the sale of organs, the question whether that should be treated similarly concerns whether banning sale would violate a constitutional right, as Lori Andrews has just suggested.

Now, I think you could construct an argument there, too, that a person has—perhaps has a right to procure a medicine or organ necessary for his or her survival. However, I don't think that would have the same support in Supreme Court cases as the right of a married couple to procreate would; so we may be able to distinguish the two on that basis.

The right of the married couple to procreate, I think has to be—has to be accepted. Ironically, enunciation of that right really arose in the birth control and abortion cases. But I think underlying those cases is a broader principle of family or marital autonomy

which includes the right of a married couple to decide whether or not to have a family, which includes their right to decide to go ahead and reproduce by coital means, if necessary, and it seems to me that if they cannot do it coitally, they would have a right to do it noncoitally.

And, thus, if that—if that right exists—if that right exists, then we have to look at restrictions that might interfere with that right. It seems to me that a ban on the sale of embryos, a ban on gestation—on paying money for gestational surrogates—might very well interfere with their ability to fulfill their marital reproductive plans.

Mr. GORE. Uh-huh.

Mr. ROBERTSON. Let's then look at the justifications for the ban. If the only justification is that we find it morally repugnant—and I share some of your sentiments about the moral repugnance of it—my point is that moral repugnance alone is not sufficient to override a fundamental constitutional right to procreate.

Mr. ANNAS. If I can add a footnote to that——

Mr. GORE. Sure.

Mr. ANNAS. Congressman. I don't read those cases as broadly as Professor Robertson reads them, and I think we still have to wait to know whether or not there is a right to procreate; that's an open question, I'll agree with that.

But the cases, it seems to me, hold that the birth control cases that if you are fertile and could produce a child, you have a right to stop, you inhibit your fertility and not become pregnant. And the abortion cases hold that if you are pregnant, you have the right to decide whether to take that pregnancy to term or to terminate the pregnancy. None of these cases have yet gone so far as to say if you cannot become pregnant naturally, you have some kind of constitutional right to go out and hire other people to help you become pregnant.

Mr. ROBERTSON. Let me just—could I for just a minute?

Mr. GORE. Sure.

Mr. ROBERTSON. Because this is a key point and may influence a lot of things in this area. I think we have to accept the fact that a married couple has a right not to be sterilized against their will. And I think the reason for that is because of their right to have children if they decide to.

So the question is, does the right to have children by coital means, natural reproduction, is it limited to that or would it include noncoital means? And think of a law where a State-banned IVF within a married couple, and ask yourself how that would be analyzed. It would seem to me that the Supreme Court cases in this area would establish a right of the married couple to use IVF within the marital relationship.

So, if there's a right to noncoital reproduction, then the question is what if one of the partners lacks what is essential, and——

Mr. GORE. Well, but—but your hypothetical only involves the—the two parents and the embryo. We're talking about a very different hypothetical here, where other persons are involved, and where a societal interest in—in avoiding the pressures brought to bear by commercial trafficking have to be considered.

Mr. ROBERTSON. Yes, I think those pressures should be looked at and if indeed there would be exploitation or social pressures, that we justify interference beyond just moral concern that—that may be sufficient. But if the only concern is the symbolic one, that it's wrong to do; we're selling people.

Mr. GORE. Uh-huh.

Mr. ROBERTSON. Then that alone, that feeling alone, without further evidence, I don't think would meet the constitutional standards.

Mr. GORE. Well, I'm not—I'm not even sure about that. I mean, I think that—that's more than just a feeling, it involves our definition of human beings: people are not property—

Mr. ROBERTSON. Well, but, but—

Mr. GORE [continuing]. And—and have never been considered such in our legal tradition, even as Professor Capron has said, and as the case law holds, that deceased individuals, bodies have never been considered property. Parts of people are not considered property.

The House and the Senate have just both spoken on that. And to say that the embryo of the human species can be considered property is—is wrong, in my view; leave aside the deleterious consequences which one can readily imagine. Flowing from that, the—the principle itself, I think, has substantial value.

Mr. ROBERTSON. Well, I think we tend to get confused by the rhetorical connotations of a term such as property or ownership. We tend to think like we own a car and object, we can destroy it or do anything we want with it. In law, property is just a term for a bundle or rights, what one is free to do with the subject of the property.

In this area, there would be—there are many limitations of what one can do with the embryo, the fetus, the child that—that results. Those restrictions would still apply, and when you—

Mr. GORE. I disagree that there's just a sliding scale or continuum with property at one point along the spectrum and human beings at another. I think there's a sharp distinction between something that is property and something that is not property. It—

Mr. ROBERTSON. Well—

Mr. GORE. It's—I mean, you can do things with property that you can't do with—with people.

Mr. ROBERTSON. See, what is being transferred here is the right to gestate and rear the embryo. It's not a right to destroy or do anything you want with it. And if you once get a child out of that there are child abuse laws, criminal laws, which apply. Property is—it's—property, I find to be a kind of rhetorical notion that has a lot of power here but when we look at the specific transaction we're talking about, we're talking about married couples having the right to—having the freedom to find someone else to help them fulfill their—their reproductive needs. The fact that they are paying them money for what is provided leads people to say, well, that's property, and that's terrible. But in actual fact, they're just transferring the ability to do the further steps.

Mr. GORE. Well, I take note of the fact that you're not—you're not saying that you as yet are sure that you believe that they should be allowed to be bought and sold; you're just raising some

reservations, and I respect that. I disagree strongly but we—we needn't belabor it too long because we've got a lot of other questions to explore.

Do you want to—

Mr. ROBERTSON. I just want to point out in the area of the gestational surrogate that there—there may be, I'm—I am more certain there the ability to pay a fee to a woman to carry the embryo of another woman who has ovaries but has lost her uterus to a hysterectomy—

Mr. GORE. Yeah.

Mr. ROBERTSON [continuing]. That the ability to pay a fee there, it seems—to another woman—in order to recruit someone so she can have a child, seems to me there I would more certainly say that that should be protected.

Mr. GORE. Well, I think it's a different sort of interest and different questions are raised. It's intriguing that the Warnock Commission has recommended the criminalization of some aspects of payment for surrogate motherhood.

Mr. Capron, what do you feel about their—have you had a chance to review? We supplied the Warnock report, which just came out a couple of weeks ago, to all of our witnesses, and doubtless, some of you had it through your own sources, but—

Mr. CAPRON. I have. The largest problem that I have with that particular conclusion of the Warnock report is that I think it is so unenforceable.

Mr. GORE. Uh.

Mr. CAPRON. It is so easy in those situations where the agreement does not break down, which is always the problem with this. But short of endorsing it and setting up the legal means whereby the contracts would be, I think, in a rather draconian way, that Professor Robertson suggests, made enforceable to the point of taking the child away from the surrogate mother; which would be contrary to Professor Annas' conclusion that any woman who bears a child should be conclusively presumed to be that child's mother. But it would be short of those situations in which it breaks down.

You can so easily imagine if you intend to have a child by a surrogate mother, you simply arrange to have her go to the physician and register as your wife. You give her your wife's birth date and social security number; she goes to a physician she doesn't know; she shows up pregnant. Or she goes to one doctor to get inseminated and another doctor to carry term; she checks into the hospital and is registered as your wife; and she walks outside with the baby and gets into the cab with you; and she gets out one door and your wife gets in the other door of the cab, and you drive off with the baby.

It would just be so difficult, it seems to me, without intruding in incredible ways into the whole process, to enforce it. I—

Mr. GORE. Well, they're not recommending the criminalization of all—that outright, they're—

Mr. CAPRON. No, no, I think you're correct, Mr. Chairman, they're representing the criminalization of agencies that—

Mr. GORE. Yes.

Mr. CAPRON [continuing]. Would recruit women.

Mr. GORE. Yes.

Mr. CAPRON. You're quite right about that. It seems very likely—

Mr. GORE. I mean, it would be easier to—to—

Mr. CAPRON. That would be somewhat easier to enforce until people start flying over to Sweden or something, and—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. Getting on a boat across the English Channel.

If you believe John Robertson's constitutional law analysis, if the woman has the right to do this, if the couple has the right to do this, then it would seem to me they have the right to employ agents for that purpose as well.

We'll wait for your box to talk to you.

Mr. GORE. Thank you.

All right, let me—

Mr. CAPRON. Do you have a little man in that box?

Mr. GORE. Pardon me?

Mr. CAPRON. Do you have a little man in there?

If I could add one other thing, it seems to me one of the complications that Professor Robertson's argument presents is the notion that he introduced—two, two parts of the notion—in which he said, "assuming we're talking about a married couple," when in fact, of course, the Supreme Court's decisions on reproductive rights explicitly are not limited to married people.

And, second, he said, "assuming fit parents." And I really do wonder if we want to get into a situation beyond what we already have with an abortion—excuse me, adoption—where the States start setting up groups of social workers, and psychologists, and psychiatrists, and who knows who else—lawyers, I suppose, and judges—to decide who can have access to which of the reproductive techniques; until the point we say, you know, hey, it's not so different than natural reproduction—a lot of parents aren't so great—we ought to screen everybody. And, indeed—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. Let's—let's take in everything else while we're at it. And I really do think that the caution that he introduces into his own analysis indicates that it's not quite as conclusive as a policy recommendation as he suggests. Those are—I regard those in the best sense of the word, John, as weasel words, indicating little red flags indicating that you're not entirely comfortable, and should not be entirely comfortable with those recommendations.

Mr. GORE. Let me give you the last word on this subject and then I want to move to another. Go ahead.

Mr. ROBERTSON. They aren't weasel words at all. My argument is based on analysis of constitutional cases and what the Supreme Court would do. It seems to me that though the Supreme Court has recognized the right of both married and single persons to avoid conception or abort, it would not follow that they would recognize the same right of married and single persons to procreate.

In my view, they would clearly recognize the right of married persons to have children. But it doesn't follow at all that they

would also recognize the right of single people to have children outside of marriage.

It's not weaseling at all, I think there's an analytic distinction there that has a basis.

Mr. GORE. All right, let's move on. I think it's based on the right of privacy but, but—another recommendation of the Warnock Commission is that the embryo of the human species should be afforded some protection in law. Does anybody disagree with that?

Mr. ANNAS. It's hard to disagree with that because you have no idea what it means. I mean, one of the problems I have, really have with the whole Warnock Commission report is, every very difficult issue, they have basically said the licensing authority that we set up is going to take care of this issue. And, obviously, and—

Mr. GORE. Well, well, it would be—

Mr. ANNAS [continuing]. And that's what they're going to do, they're going to take care of the research issue as well. You can—

Mr. GORE. Maybe—maybe I'm reading this—maybe I'm reading this statement in—in too broad a sense. Here is—here's where I'm—well, here's what I'm thinking of: In many of these dilemmas, in many of these situations, the decision comes down in a way that seems to afford no protection in law, or no substantial consideration of any rights adhering to the—to the embryo. I mean, that's true, isn't it? I mean, in—in many of these cases, the decision is made in a way that sort of assumes that there are no rights afforded to the embryo. Isn't that the shorthand way that they—

Mr. ROBERTSON. Well, I think you have to distinguish cases in which the embryo is going to be implanted in cases where it's not. In cases where it's going to be implanted, whatever you do will affect the future child, and that future child clearly would have rights to be protected. So, protection of the embryo gets confused or merged with protection of this future child.

So the issue really arises, then, when, if you're not going to implant the embryo—

Mr. GORE. Yes.

Mr. ROBERTSON [continuing]. Should it be protected?

Mr. GORE. Yes.

If the embryo is not going to be implanted, should it, nevertheless, have some protection in law?

Mr. CAPRON. I would answer that question "yes." And I—I think that in the end one comes down to what Professor Robertson was referring to before, is simply one's moral sense as to what is fair and decent to do to another human entity, not yet a full person, a born baby. And I think that society makes a lot of judgments on that, so that we don't have to apologize to them. We have to explain them, and we have to engage in the kind of analysis that he's challenging us to make. But in the end, the fact that you would simply say, there's a moral revulsion against treating a potential human entity that isn't going to be carried to term in a way that's disrespectful, and using it for trivial research doesn't strike me as—as wrong just because it's based on a moral revulsion.

Mr. ROBERTSON. And I would agree with that. When we're dealing with the embryo that is not going to be implanted, then we will not be interfering with procreative rights. And if the State wants

to promote respect for human life in this way, that's perfectly legitimate.

Mr. GORE. Well—Ms. Andrews.

Ms. ANDREWS. Well, the Warnock committee report was not that different from the Ethics Advisory Board—

Mr. GORE. Yes.

Ms. ANDREWS [continuing]. In this country in terms of the—I think it's the Advisory Board recommendation that the embryo be entitled to profound respect. And I think that the way the State laws have handled this is to say what purpose are we talking about? And there are clearly protections in 25 States against certain types of experimentation on embryos. Even if a couple's right to privacy was held to govern this area, we might want to protect embryos against the splitting to create several individuals of identical genetic makeup, or the gestation of an embryo in a—an animal surrogate carrier.

There are—you know, there are many things. But I think an important point with respect to needing to legislate in this area is that we have nowhere to turn when many of these questions are being raised like: Does a frozen embryo have a right to be born?

We can look to the Supreme Court cases, but they don't get us very far in that respect. I mean, it's one thing to say a woman has a right to terminate an embryo once it's inside of her; but once it's outside, does that embryo have some other rights? Does the sperm donor have a right to direct the course of the embryo?

We need new laws to cover these issues.

Mr. GORE. All right. We've got a lot of other questions and—and we've got a vote on, so I hate to—you know, these final days before recess are busy ones. With your indulgence, we're going to recess for another 8—8 to 9 minutes, and come back in.

[Recess.]

Mr. GORE. The subcommittee will come back to order, please.

We were just discussing before—before the recess, the subject of whether or not human embryos should be afforded protection in law and, if so, to what extent. The general consensus on this panel seems to be yes in principle. But the definition of the right afforded the embryo seems to be confined to a right to be respected and treated with dignity whenever other interests do not prevent that.

Am I stating that too harshly, or is that essentially correct?

Mr. ANNAS. I think you can get into some trouble using the term rights. I don't think we should think of embryos having rights—

Mr. GORE. Ah, now, wait a minute.

Mr. ANNAS [continuing]. In the traditional legal sense that they have standings to—

Mr. GORE. Well, let's back up then, because the initial question along this—in this line of questions was whether or not anyone disagreed with—with the conclusion of the Warnock Commission, and with the conclusion on the part of others, the advisory committee here in the United States, that embryo should be afforded some protection—

Mr. ANNAS. Protections, I think, is—

Mr. GORE [continuing]. In law.

Mr. ANNAS [continuing]. Is OK.

Mr. GORE. Oh, OK.

Mr. ANNAS. I just—I'm just objecting to the notion that embryos have rights. If you think of that, society wants to protect them for its own purposes, I think that's—

Mr. GORE. Well, a right to protection.

Mr. ANNAS. OK.

Mr. GORE. I mean, I don't want to quibble about words, but to some extent they're very similar, aren't they?

Mr. ANNAS. Well, I just—in a more traditional sense a right is—has been something that you have standing to bring a lawsuit about, and you can—whatever, remedies have flow to you—

Mr. GORE. No, it's not confined to that. I mean—

Mr. ANNAS. It's not confined to that, but I mean, that's—

Mr. CAPRON. I would agree with—with the chairman in saying that the suggestion would be if you created a statutory right—and I think that's what George is saying—we, in this country, use the term right for those things which flow from the Constitution as well; and which, even if society didn't start off wanting to protect, the court might well order.

Mr. GORE. Yeah.

Mr. CAPRON. This is the right of the embryo not to have X, Y, Z done to it. And I would agree with Professor Annas, that if you get to a situation you are talking about that, that that doesn't sound like what we ought to be talking about; society would have good reasons to have protections, and then there could be a protector who would enforce that if you want to call it right, to have the statute respected—

Mr. GORE. Uh-huh.

Mr. CAPRON [continuing]. If that's what the question is. And someone comes into the lab and starts doing horrible things to the embryos, you'd say, you're protecting their right to be protected—

Mr. GORE. Yes.

Mr. CAPRON [continuing]. As recognized by society.

Mr. GORE. Yes. But—but your definition of the right afforded to the embryo, or the protection afforded to the embryo, is very limited; it's limited only to the right to expect—the right to be respected—

Mr. CAPRON. That's—that's in the context of the embryo, it's not going to be implanted—

Mr. GORE. Yes.

Mr. CAPRON. I think—

Mr. GORE. OK, let's confine it to that—

Mr. CAPRON. It should be very clear that that's what we're talking about.

Mr. GORE. That's fine.

Mr. CAPRON. Physical protection for future life is a much stronger protection for those that are going to be implanted.

Mr. GORE. Correct; and lawsuits can be brought for damage to the embryo, et cetera, et cetera. But, for embryos that are not intended to be implanted, the only right which you are willing to grant the embryo is the right to be respected and treated with dignity when other interests of society don't—don't interfere, such as the desire to experiment in pursuit of useful knowledge.

Mr. CAPRON. I think that's right. There are so many qualifiers in that long statement, as inevitably there must be when one is talking about an abstract—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. As you are now. That although I wouldn't be as harsh as Professor Annas was about, well, all these in the Warnock report were delegated to that committee, it does take a body to really sit down and work out some fairly—

Mr. GORE. Case by case.

Mr. CAPRON [continuing]. Case by—well, there may be some generic rules; but they would be guided by the kinds of principles you're talking about. But the fact that the principles are not precise at the moment doesn't mean they're vacuous. The notion that respect, because this is a human entity—

Mr. GORE. Yes.

Mr. CAPRON [continuing]. Means something more than just good lab procedures because society wants to do some research, I think has a content to it. You could well say that you have to have greater respect than you do for hamsters. I know I'm going to bring the animal rights people down for that, but—

Mr. ROBERTSON. It seems to me that there are two issues that arise here that may be of concern. One is a major one for the Warnock committee was whether you could bring embryos into being solely for the purposes of experimentation. That was a major block for them; they divided over that. So, if—

Mr. GORE. Whether you could what?

Mr. ROBERTSON. Whether you could create embryos with no intent—

Mr. GORE. Yes.

Mr. ROBERTSON [continuing]. To ever implant them; merely bring them into bringing—

Mr. GORE. Yeah.

Mr. ROBERTSON [continuing]. For the purposes of experimentation. Does that show sufficient respect for this human entity? So, that's one issue here. And I take it that if we once have the embryo, it's a surplus not used, not going to be implanted. And if we think research on it is possible, is permissible then, then I don't see the distinction that some of the Warnock committee members made that we should not bring embryos into being solely for the purposes of experimentation.

Mr. GORE. Do you disagree with that?

Mr. ROBERTSON. Well, I go with the majority of the Warnock committee which says that we can bring them into being for the purposes of experimentation if they're good, valid experiments that need to be done. It doesn't matter how we got them as long as there's good reason for using them.

Mr. CAPRON. It strikes me that there is a slippery slope that we're on when—with that rationale, however, because the example that you were exploring with some of the scientists earlier, of the division of an early embryo, when it is still—or early blastocyst, when it is still at the 2, 4, 6, 8 cell level—and the culturing of some of the cells to create a being that's going to exist, and the saving of the others, for example, as a tissue bank—

Mr. GORE. Yes.

Mr. CAPRON [continuing]. Strikes me as raising concerns about is that the kind of respect you want. And I can see it being met on the one hand with an argument that I would regard as a little too clever of saying, well, you're not treating a separate entity that way, it's just that the individual who is going to be born has had a few things set aside out of its own genetic makeup. Unfortunately, that's the way twins are created, after all. And it's as though you are having a twin entity, which is solely going to be used—and created for the purpose of being used as an organ bank.

Mr. GORE. Like the coma scenario?

Mr. CAPRON. Exactly. And I'm bothered by that. And it may be that Professor Robertson or others could say that it was only my gut responding, but I would listen a little bit to my gut, at least at first, in saying—

Mr. GORE. Now, Professor Robertson may not be in favor of that.

Mr. CAPRON. Well—

Mr. ROBERTSON. I'm—nothing wrong with gut reactions; we all have them all the time. It's just there's certain limits on the State translating them into law.

Ms. ANDREWS. Well, I think the limits are far less in this area than in the area of treating an infertile couple where the right to procreate may come into effect. I mean, I think that there's far more of a legitimate role for the State to ban experimentation and use of embryos. I don't find it convincing that just because a woman can terminate during the pregnancy that that right should be allowed once the embryo is outside of her body, although it seems to be interpreted along those ways, in at least the attorney general opinion in Illinois and a few things that have dealt with it.

Mr. GORE. Well, it's my impression that in practice—and I know this is thin ice, the whole subject is thin ice—but it's my impression that in practice the right, or protection afforded the embryo when these decisions are made, is often assumed to be negligible.

Is that impression wrong?

Ms. ANDREWS. I mean, I don't see how you can say that when there are so many States that just say you cannot do experimentation on embryos; and that's a pretty strong protection.

Mr. GORE. No, no; I'm saying when the decision is made in the laboratory, or in the hospital, States have enacted such laws because they express the gut feelings of the people in those States. And many States have moved far more rapidly in this area than the Federal Government has, or should. Rich Fitzpatrick, a representative from Michigan, who has played a leading role there, is here.

But when I say that when the decisions are made, those rights are assumed to be negligible, I'm not talking about the passage of laws; I'm talking about the decisions of the scientists and doctors.

Ms. ANDREWS. Well, we had heard at a conference in Boston just a few months ago that there were many scientists in Massachusetts who were not pursuing particular types of research because of their fetal research laws; and so it does have a practical effect in the laboratory.

The Illinois law governing in vitro fertilization and restricting what physicians can do has had a practical effect, and people in Illinois are not freezing because of this law. So to a certain extent,

when physicians are aware of the law, they are having it govern their behavior and prohibiting certain work on embryos that they would care to do.

Mr. CAPRON. If you're asking about the situation in the absence of the laws, I'm not in a position to say that I conducted a study—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. Of the attitudes or behaviors of all the embryologists in the country.

Mr. GORE. Yeah.

Mr. CAPRON. But my suspicion, however, is that one would not expect them to be immune to the considerable ethical debate that has gone on on that level, although they might very well decline to put in terms of rights, as Professor Annas did a moment ago, of the rights of the embryo, but some notion that they are dealing with something more than just a clump of cells that are cultured out of a cancer cell of somebody that's being studied in cell culture.

And I would not expect—I would not go in with the presumption that they are not having careful concern and consideration of the type that you heard was going on at Vanderbilt, which permeates the thinking of the scientists. Whether a broader basis outside the scientific community is needed to make clear what the expectations of society are, and perhaps to police them in some way, is another question. I'm not saying that's necessarily an adequate standard, but I doubt that it is their thought that "coat the embryos that without rights that I'm just dealing with a little human protoplasm."

Mr. GORE. OK, that's—that's fair enough, that's fair enough; and probably more fair than my earlier statement.

Let me move on to another subject. The obligation to screen—if embryos are created outside the body, under what circumstances would the medical professionals involved have an obligation to take advantage of that extracorporeal state to, in a nonintrusive way, screen that—that embryo? Obviously, it's a very complex question with a lot of things involved.

You brought it up in your statement, Mr. Capron, why don't you begin?

Mr. CAPRON. Well, I was focusing there particularly on the actually the screening of the people who were contributing the genetic material. If you talk about screening the embryo, I think that you have two things that work. The first is the desire and wish of the parents-to-be. There would be some people in a situation who, I think, Mr. Chairman, would say we don't care—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. We want every embryo, no matter what its condition, implanted. And if nature doesn't destroy it in the process of gestation, we want it to be born.

Mr. GORE. Yeah.

Mr. CAPRON. The second thing, of course, is that it's not probably going to be any different than other areas of medicine; that is to say, the basic standards as to what is medically expected good behavior on the part of physicians is set by physicians. Just because a university researcher develops a new genetic test does not mean

that every obstetrician in the country is expected to start using it immediately.

Mr. GORE. Yeah.

Mr. CAPRON. There is, on the other end of the spectrum, a time when things are part of standard expectations of decent medical practice, of whether the physician is judged negligent for failing to use it.

And so that professional standard and the wishes of the parents, it would seem to me, would be the major guidance.

Ms. ANDREWS. So it would never be an obligation of the physician to screen; it would be an obligation—

Mr. CAPRON. To inform.

Ms. ANDREWS [continuing]. To inform the potential parents of the availability of the technique to let them know about.

Mr. GORE. OK, I think that's a good answer.

Now, what about the hypothetical I discussed with the earlier panel about cloning of embryos, or twinning of embryos, if you prefer? I think technically it is cloning. But is that—can you conceive of any circumstances where you would think that would be all right? Or, alternatively, can you conceive of any circumstances where the society as a whole would have the right to say to those who requested such a procedure, no, you can't do that?

Mr. ROBERTSON. Well, continuing my line of analysis, we're talking simply about twinning—there's a right to procreate a single child noncoitally, I think there would be the right to have two children at the same time. I think that would follow if—

Mr. GORE. Or 10, right?

Mr. ROBERTSON. Well, well, if you say why not 10—you have to ask, well, what's wrong with 10, OK? And if you can come up with some reason why 10 is bad, if it will kill the woman, maybe that would be sufficient.

Mr. CAPRON. Well, you don't have to do them all at once, you can freeze them and do one every year.

Ms. ANDREWS. You know, I think that in talking to the infertile couples who are potentially interested in that procedure, I mean, they make the argument that why subject the woman to an additional laparoscopy; another \$4,500 to \$6,000 of cost to go through another cycle of in vitro fertilization—

Mr. GORE. No, no, no, wait a minute. We're talking about—

Ms. ANDREWS [continuing]. To 10 and have them put—to twin the embryo and have it put in at the same time.

Mr. GORE. I'm not talking—

Ms. ANDREWS. So, that's a situation where it possibly could be used in a way that society might approve of.

Mr. GORE. Well, why wouldn't—I mean, to serve that particular right or concern, would be much easier and less risky to simply implant two embryos to avoid—

Ms. ANDREWS. No, if only one is dividing correctly. For example, if only one—if they've only got one embryo, say, that is normal, should a couple have a right to have that embryo split, that would be seem to be—

Mr. GORE. Oh, I see.

Ms. ANDREWS [continuing]. The strongest case for splitting the embryo.

Mr. GORE. Uh-huh.

Ms. ANDREWS. But I certainly think there are—I have grave reservations about along the use of the splitting technology, particularly when you're making suggestions that you could bank one, wait till one grows up and gets into Harvard, or whatever, and then decide whether you want to——

Mr. CAPRON. Or Vanderbilt.

Ms. ANDREWS [continuing]. Gestate the other one.

Mr. GORE. Or Vanderbilt, that's right. [Laughter.]

Mr. CAPRON. Do you have to—is it your alma mater or your district that's more important right now?

Mr. GORE. Be careful, Mr. Capron. [Laughter.]

Ms. ANDREWS. Or, you know——

Mr. GORE. Now you've gone from being helpful to meddling. [Laughter.]

Mr. CAPRON. Do you want to strike that?

Mr. GORE. From the record, yes, please strike that.

Ms. ANDREWS. I mean, I think that this sort of psychological harm about not having the right to an independent, individual identity may be just the sort of harm that would outweigh, a compelling State interest, even in a right to procreate. And so I can see the acceptance of bans on the use of that particular technique.

Mr. GORE. OK. Well, let's take it from the other direction, then. Mr. Capron, what's wrong with it?

Mr. CAPRON. What's wrong with the suggestion she just made?

Mr. GORE. Let's say—let's say—let me give you the hypothetical.

Mr. CAPRON. The hypothetical that she just gave you would have you opening up baby magazines and saying, you know, sort of proven road model. This—this—look how wonderful this kid—just won a—an Olympic gold medal. You, too, can have one of the same proven stock and, indeed, you can have his—his twin brother 20 years later.

Mr. GORE. I share your abhorrence for it. Now, try to articulate beyond the gut level exactly why that is abhorrent.

Mr. CAPRON. Because I think you would almost certainly find that the harm to the children in becoming that kind of a commodity, having to live up to certain expectations, being treated totally as a means of gratifying certain wishes on the part of other people, would be a good—to me, that's a good enough argument; that goes beyond a gut feeling.

Now, I would agree that in order to be moved very far by that you would have to support it with psychological analysis, sociological analysis, and so forth. But it seems to me that on the surface of it, it seems very likely that's the case.

Mr. GORE. I mean, do we have to go——

Mr. CAPRON. I can tell by the stirring to my right this is creating some——

Mr. GORE [continuing]. I mean, can't we get there—can't we get to the reason for the abhorrence by another route without—without relying on the damage to the children? Isn't there a societal interest in preventing that sort of procreation?

Mr. ANNAS. I mean, I think you're back to the stuff we talked about sales—you weren't here, but—you know, the commercializa-

tion aspect. And as Alex said, treating the child like a commodity—

Mr. GORE. Yeah.

Mr. ANNAS [continuing]. I think that's exactly what it does. You know, and, you know, you can envision one of the problems I have with sales is precisely this. You can envision catalogs of embryos, and if you can split them or twin them, you could get identical embryos.

Mr. GORE. Yeah.

Mr. ANNAS. You could, after the Olympics, you could, you know, get Mitch Gaylord's sperm and cross it with Mary Lou Retton eggs, and I'm sure that would sell very well, because a lot of parents would like their kids to be gymnasts and they probably have a reasonable chance to get that, as Alex would say.

Mr. CAPRON. Well, you see, George, it would even—I agree with what you're saying, but you go beyond that, because you combine on basically the genetic lottery. It's like the famous comment of George Bernard Shaw when Isadore Duncan suggested to him—I believe it was Isadore Duncan—why don't you and I have a baby? It would have your brains and my looks. And he said, yes, madam, but have you considered the opposite possibility?

And the same kind of thing could happen; it could end up not like Mitch—

Mr. ANNAS. Gaylord.

Mr. CAPRON [continuing]. Gaylord, and Mary Lou Retton. But if you had Mitch Gaylord's twin, in fact, dozens of them sitting in the freezer, then the probability—you already know the genetic makeup; so I think that carries it, George, the step further.

Ms. ANDREWS. But, George, you're mixing up commercialization and eugenics; because if you look at it, the Nobel Prize sperm bank charges nothing for its sperm as opposed to sperm banks—

Mr. ANNAS. And likely is going to be completely ineffective—

Ms. ANDREWS [continuing]. And medical students, you know, which charge \$70.

Mr. ANNAS [continuing]. In doing what it wants to do, too. I mean, that—

Ms. ANDREWS. I mean, that's—that's another issue. I mean, it depends what your, you know, fears are, and—

Mr. ANNAS. My fears are treating humans as commodities, as I expressed them. And if you can figure out what the commodity is, then you treat it as a commodity, if you're right. If you're crossing eggs and sperm, you don't really know what you're going to get. If you clone or twin something, you know—

Mr. CAPRON. You can't have a commodity without payment of price too.

Mr. GORE. OK, hold on just a second, Professor Robertson wants to jump into this.

Mr. ROBERTSON. I would like to suggest that this issue you raise now is, I think, going to be the most troublesome in this area—this notion of to what extent is there a right to select or control the characteristics of your offspring. At first blush, it seems horrible, and I agree. Yet, that is precisely the freedom that we grant par-

ents in rearing their children. They can control, influence, determine—

Mr. GORE. Not precisely.

Mr. ROBERTSON [continuing]. Characteristics. Not—not precisely; parents differ in that, and parents have expectations which are often disappointed. They send their kids to special schools, camps, whatever, and there's always the possibility that the kid won't turn out to be the way the parent wants. And yet we tolerate that as part of the parents' rearing freedom.

We also tolerate parents—I think we will intervention at the genetic level if it's for the purpose of curing a genetic defect, of curing a genetic disease.

I wasn't at your hearings on gene therapy, but from my reading of the literature there, there is the recognition that a parent would have a right to alter the genes of a child to remove a serious genetic defect that would allow that child to live.

Mr. GORE. Well, it's a different, it's—certainly that's the case. But with embryos, a different question is raised, and that is the effect on future generations, because genetic alterations at the embryonic stage are—usually germ line alterations and, in fact, in every case, I guess, by definition. So the interests of future generations are also involved.

Mr. ROBERTSON. Well, except it's hard to see how a future generation deprived of, say, the Tay-Sachs gene because of a germinal intervention—

Mr. GORE. It is indeed, but you're familiar with the sickle cell—

Mr. ROBERTSON. Right.

Mr. GORE [continuing]. Hypothetical—

Mr. ROBERTSON. Sure.

Mr. GORE [continuing]. Where there is some conceivable use for the sickle gene, although it could probably be preserved cryogenetically or some other—

Mr. ROBERTSON. Sure.

Mr. GORE [continuing]. Way, instead of having it inflicted upon living human beings.

Mr. ROBERTSON. My point in raising this is not to get off into that, but to point out that there are traditions, or accepted practices, in our society where we do allow parents, after birth, to rear, to influence, determine characteristics significantly. And there will be, in the course of birth, in utero fetal therapy or even genetic therapy to cure genetic defects.

And so those traditions set up some pressure here for some recognition of a parental right to go further. Now, I'm troubled by that, too, and there are a lot of questions about that. That's why I say it's perhaps the most troublesome issue here.

But I don't think we can overlook that background in dealing with this issue. And if we don't see harm to the child from these efforts—and often that might not exist; maybe Alex's social studies will show real harm—but if we don't have harm, we come back to the moral compunction that is important in our society, and the question of to what extent the State can use that to intervene.

Mr. GORE. OK.

Mr. CAPRON. I don't want to have this become the Robertson-Capron debate, but it does seem to me that you have here an example of what I was trying to argue about creative preservation. If we recognize that, yes, sometimes parents do things—the stage-mother syndrome—they do things to their kid that really isn't very good for the kid.

On balance, we don't think that society would be the kind of society in which we would want to live in which the State was constantly intervening in that process, because who would know better—we'd have to have some very wise person that would know better than every parent. But that's different than saying we basically value the notion that children should be given a little more freedom than that, and should not just be blueprinted by their parents.

Why take another step that goes in that direction? Why not look at that and be more critical of it when it involves a much more blatant example of that kind of a step which would, in being prevented, would not necessarily involve the State as pervasively in all the myriads of choices about what school you send your kid to; and do you make the kid have piano lessons, and learn to be a gymnast, or whatever it is.

Sure, there are those kinds of things which in a diverse society that is not totalitarian, we very strongly believe should be left to families. But that doesn't necessarily mean because we tolerate that and indeed respect it, that we should also say that you can buy kids out of a catalog, which really carries that whole notion of—of children being just living for their parents and having a certain blueprint they have to follow. And if your kid, who's supposed to be Beethoven, doesn't turn out to play the piano, you're really, you know, whether you'll be, as George Annas says, you'll take it back and say "my warranty's been breached;" or you'll do something else—horrible—trade it into a new model—or you'll do something horrible to that kid. It seems to me, why take another step?

We really ought to try to preserve the better values and recognize the potential harm that would come—

Mr. GORE. Yeah.

Mr. CAPRON [continuing]. In going in that direction.

Mr. GORE. OK, one other comment and let me move on to another subject.

Mr. ROBERTSON. Just a—yet, you would not prohibit us from choosing marriage reproductive partners as we wish.

Mr. CAPRON. No, it—

Mr. ROBERTSON [continuing]. For precisely reasons of wanting a certain kind of offspring.

Mr. CAPRON. I'm not talking necessarily about prohibition—that's what I said, the idea of the creative preservation works to preserve the value even if you say there may be a few cases where this technique is justifiable to be used. The free—the splitting, and freezing, and have one—and having another one in the freezer, as it were.

But we don't—we want to do everything we can to reinforce society's basic impulse to say this is not going to be a commercial practice—

Mr. GORE. Uh-huh.

Mr. CAPRON [continuing]. Even if there were reasons why we felt we couldn't regulate it and absolutely prohibit it.

Mr. GORE. The ability to freeze eggs would solve some of these problems because it would obviate the necessity to freeze embryos in many of the circumstances where they—where that procedure is now considered.

On the—on the choice of what to do, let's take the example of the Melbourne embryos, where you have embryos that are left over, you don't—well, let's don't take that example, because there are too many things involved there.

But let's take the example of frozen embryos where the parents have successfully given birth to a child and do not want, or need, the other embryos. What do you do with those other embryos, and how do you go about deciding it? Professor Capron.

Mr. CAPRON. I would say that as to the two possible uses—one would be to have the embryo used—three, I guess—the uses would be to have it used in research at the choice of the parents; to have it implanted in someone else on an anonymous donor basis, just the way the egg or sperm would be; or to have it destroyed, which is not a use but a nonuse.

All three of those seem to me acceptable. And you overcome, in that case, what is, I think, a reasonable moral concern about creating embryos for the purpose of research, because in this case they weren't created for that reason. But the parents in effect saying, we were able to benefit from these researchers' past experiments, we now want to do something for research and we don't regard that as—you know, as long as there's an ethical review committee, and so forth, saying that this experiment is being done correctly, and it's for a justifiable—and cannot be gained otherwise—we would consent to that use. Now, that seems to me, acceptable.

Likewise, if they want to make that donation, that does not seem to me to be a problem, except for all the reasons that we've already outlined, that the law doesn't know a lot about what later consequences that could have legally for them as far as being at least the genetic parents of that child. But that's not a reason why that's unacceptable; it just means we have to have a means of dealing with that, and with AID, and with egg transfers.

Mr. GORE. Mr. Annas?

Mr. ANNAS. Are the parents still alive in your hypothetical?

Mr. GORE. Yeah.

Mr. ANNAS. Yeah; then I'd leave it up to the parents, I agree with Professor Capron.

Mr. GORE. So let them decide?

Mr. ANNAS. The parents are dead, though I would require the embryo to be destroyed, they haven't made other provisions for it.

Mr. ROBERTSON. I would agree, too, unless you wanted to take seriously the notion of respect for embryos; respect for embryos would mean you don't destroy them.

Mr. GORE. Uh-huh.

Mr. ROBERTSON. And even if the parents, that genetic source, wanted them destroyed; respect for embryos would mean that you preserve them for adoption by someone at a later point, or you have them adopted now without the consent of the source, if you're

truly concerned about respect for embryos, that would be a course you could take.

I suggest it may be constitutional, it's unclear; but that would be a policy option. I wouldn't recommend that myself now, but other than I pointed out.

Mr. GORE. Uh-huh. Well, it's not—I mean, when you use the word "respect" there, the other side of the same coin, it's not—it's not an absolute thing that drives you toward a predetermined outcome. But it would, given a range of choices, each of equal weight, perhaps push you in the direction of—of implanting, or adopting, or whatever you want to call it.

Ms. ANDREWS. The Royal College of Obstetricians and Gynecologists suggest yet a different approach in England and their recommendations. They feel that once a child has been conceived and born through one of these technologies, you should not use the frozen embryo to create a child for another couple because they have a concern about siblings out there, and we really haven't touched on that today. But these new technologies do bring up that issue.

Mr. GORE. If there is—let me—let me state it another way. If—if other concerns mandate confidentiality of information, then the society has an interest in genetic diversity and the avoidance of genetic flaws from—from siblings—

Mr. CAPRON. Intermarriage?

Mr. GORE [continuing]. Intermarrying later in life to—obviously a small risk.

Mr. CAPRON. That's the same kind of thing that happens now when orphans are adopted by more than one family, which has been—it's less prevalent today because there are fewer children for adoption. But that can be handled, I think, perfectly adequately if we had a decent recordkeeping system.

The problem in the past has been that these new means of conception have all been done on a basis that doesn't allow record-keeping.

Ms. ANDREWS. Now if there were certain physical limits to the number of children you could create and that were available as orphans—now if a man donates sperm twice a week; at this current success rate, he could create—

Mr. CAPRON. Right.

Ms. ANDREWS [continuing]. Over 150 children a year. Biologically, it's possible for him to create 20,000 a year. And with embryo splitting, you might also give rise to the possibility of embryo—of intermarriage in these instances—

Mr. CAPRON. With embryo splitting, there wouldn't be intermarriage because you'd have children that were identical. [Laughter.]

Ms. ANDREWS. My—my question, though, is what—what sort of record—what would recordkeeping help? Then you'd like tattoo people so they wouldn't marry someone else that had the same donors?

Mr. CAPRON. Well—

Ms. ANDREWS. I mean, how is that going to help without abridging other rights?

Mr. CAPRON. Well, I don't know that it bridges your—your right. It probably would be the kind of thing that if it—if all this became

much more prevalent, I think it would—today, we look at adoption. And people today generally tell children that they are adopted. And it's done; there's all sorts of counseling that goes along with that; and it's done in a way which is not harmful to the children and, indeed, I guess the general view is it's more harmful not to know.

And I don't know why we wouldn't get to the same point vis-a-vis these artificial means; that children could learn that they came into the world that way; and a physician knew who their natural parent was, if that became an issue.

Mr. GORE. OK.

Mr. CAPRON. Tomorrow looks like an interesting hearing.

Mr. GORE. Let me—let me say to you all that I would love to pursue a lot of these other questions with all of you because they're fascinating, but it's been a long day. And there are matters on the floor that I'm going to have to get to; and we have a long day tomorrow, and it should be very interesting, yes.

Our first panel will be made up of Dr. John Buster, who pioneered the lavage technique; accompanied by the first woman to donate a fertilized egg through that technique. And Dr. Richard Marrs, accompanied by the first woman to receive a frozen embryo in this country; and she is with us today, which we appreciate, and we will look forward to talking with her tomorrow.

The second panel will be made up of Dr. LeRoy Walters, director of the Center for Bioethics at Georgetown, who has also been here today; Dr. Richard McCormick, at the same Kennedy Institute of Ethics; Prof. Samuel Gorovitz, from the department of philosophy at the University of Maryland; and Dr. Donald McCarthy, director of education at the Pope John XXIII Center.

So I'd like to close today's hearing by expressing my thanks to all the witnesses, and expressing my thanks to members of this last panel for your help.

Dr. Capron, I want to note for the record and for those present who are interested in such matters that you are putting together a meeting in October of the American Society of Law and Medicine, which will address these questions. My best wishes to you in that conference, and my thanks for your help today.

Mr. CAPRON. Thank you.

Mr. GORE. And thanks to all of the witnesses today.

We will be back here tomorrow in this same room at 9:30 in the morning. Until then, we will stand in recess.

[Whereupon, at 4:05 p.m., the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, August 9, 1984.]

HUMAN EMBRYO TRANSFER

THURSDAY, AUGUST 9, 1984

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore (chairman of the subcommittee) presiding.

Mr. GORE. The subcommittee will come back to order.

I would like to welcome all of our witnesses and guests here today for the second day of these hearings. Yesterday we began a journey exploring the ramifications of the new-found ability to create a conceptus or embryo outside the human womb. As we heard from distinguished scientists about how the ability of the new reproductive technology will enable infertile couples to have children, we marveled at the wonders of science, and, indeed, many of the questions raised will pale into insignificance when confronted with the joy and happiness of parents able to conceive who could not conceive in the past.

However, as the testimony progressed, it was clear that we have not as yet thought out in a comprehensive manner the troubling ethical and legal problems created by the actual and potential applications of this new technology. The time is clearly right for a comprehensive examination of the questions associated with the applications of these new technologies. And the word "application" is an essential point in our inquiry because while science is generally neutral, technology or the applications of basic knowledge is where the conflicts begin.

Yesterday's testimony focused on the development, applications, and rapid growth of in vitro fertilization and embryo transfer. Today we turn our attention to two new developments in this rapidly moving field. In vitro fertilization associated with cryopreservation or the freezing of embryos and lavage or embryo transfer from one woman to another.

The successful application of cryopreservation, the ability to store a conceptus perhaps indefinitely and to thereafter transfer the conceptus to a womb where it can develop to term, has added a whole new dimension to the ethical and legal issues for we may now possess the ability to have our children born over several generations.

Fortunately, to help us with our exploration of cryopreservation we have with us today Dr. Richard Marrs, the pioneer of cryopres-

ervation in the United States, and Mrs. Diana Bassi, a patient of Dr. Marrs, who received a frozen embryo.

The use of the lavage procedure also raises additional questions. Medically, some asserted the greater safety of lavage in contrast to in vitro fertilization. However, the Warmach report, the British study which we heard yesterday, has recommended for safety reasons a prohibition on lavage at this time. Controversy had also surrounded the lavage procedure because a U.S. company who funded the development of the procedure is seeking to obtain exclusive patent rights on it.

We are also fortunate to have with us today the developer of the lavage process, Dr. John Buster, and Cynthia Imhof, who was the first person to donate a fertilized egg in Dr. Buster's program.

We will conclude today's hearing with a panel of eminent ethicists who promise to challenge us as we look carefully at the conflicts and values presented by the applications of these scientific developments. I look forward to what I hope and expect will be a stimulating and challenging dialog.

I want to ask unanimous consent that the statement of the distinguished ranking minority member, Mr. Skeen, be included in the record, and the statements of other members as they are submitted.

Mr. GORE. Now, at this point, I would like to call our first panel to the witness table. Dr. John Buster, who has joined us at the witness table, and Cynthia Imhof—or Cindy Imhof, who has joined us at the witness table. Dr. Richard Marrs, if you would come forward to the witness table, along with Mrs. Diana Bassi, a patient of Dr. Marrs.

And we would also like to have at the witness table, joining us on this panel, Mrs. Barbara Brooks, a patient of Dr. Jones, who was introduced in yesterday's proceeding in a manner that she seems to not dislike at all, the oldest mother of an in vitro baby, and we would like to welcome Daniel, 4 months old, as a reminder of the wonderful results of this technology.

Let me begin by saying to all of you, your prepared statements will be included in the record in full. If you want to summarize any portion of it, certainly feel free to do that, and we are going to hold off on questions for you until all of you have completed your statements.

We will begin with Dr. John Buster. Dr. Buster is from the Harbor UCLA Medical Center in Torrance, CA. Dr. Buster has pioneered the lavage procedure here in the United States, and we are delighted to have you here, Dr. Buster, and we invite you to proceed.

STATEMENTS OF JOHN E. BUSTER, M.D., HARBOR UCLA MEDICAL CENTER; CYNTHIA IMHOF, PATIENT; RICHARD MARRS, M.D., WOMEN'S HOSPITAL; DIANA BASSI, PATIENT; AND BARBARA BROOKS, PATIENT

Dr. BUSTER. Mr. Gore, ladies and gentlemen, good morning. My name is John Buster. I am a professor of obstetrics and gynecology at the UCLA School of Medicine at the Harbor Hospital Campus in Torrance, CA.

Earlier this year, our team at the Harbor-UCLA Medical Center announced the birth of two healthy children to each of two women who had been infertile and untreatable by standard methodologies. The process utilized to start these two pregnancies was nonsurgical human ovum transfer, a technique developed by our group through a research contract financed through private funds.

Six months later, the families are supremely delighted with these beautiful children, and we are looking forward to offering this new technique to the many infertile women who will benefit from it.

The purpose of my presentation is to introduce the members of the subcommittee to the technology of the nonsurgical human ovum transfer process, the safeguards we have implemented and the moral, legal, and ethical issues that surround this work.

The ovum transfer process is a technique offered to infertile women whose infertility is due to untreatable disease of the fallopian tubes. It uses an egg donated by another woman. It is performed in five steps.

May I have the lights down please, and the projector.

[Slide.]

Dr. BUSTER. This first slide is the announcement of the first two births in the history of the world by our process. We actually announced this to the public on February 4, 1984.

This first slide illustrates the first step in the nonsurgical ovum transfer process. The first step is to synchronize the ovulation dates of the infertile recipient woman, preferably to within plus or minus 2 days, with that of the donor.

In our program, this was done by having a number of spontaneously ovulating donors and recipients who could give and receive each others' eggs.

[Slide.]

Dr. BUSTER. The second step is to inseminate the fertile donor with semen from the husband of the infertile patient. Conception takes place in the body of the donor.

The third step, lavage or washing out of the uterus of the donor, takes place 5 days later. Recovery of the fertilized egg is possible because it is free floating in the donor's uterus. This is a virtually painless office procedure that takes about 5 minutes.

The fourth step is to recover the fertilized ovum in the lavage fluid. Appreciate that the fertilized egg is a structure of 130 microns, ideally would have about 100 cells in it. It is a hollow ball, and I will show you a picture of an actual fertilized ovum a bit later.

The fifth step is to transfer the fertilized ovum into the uterus of the infertile recipient. This also is simple and painless. If all goes well, the fertilized ovum attaches to the wall of the infertile woman's uterus, and 9 months later the woman gives birth to a child that is fathered by her husband but arises from a donated egg. So this slide summarizes those features. It is medically simple, ultimately a high probability of success, low risk, a nonsurgical office procedure and analogous to donor artificial insemination.

Indeed, from a legal point of view, it is analogous to donor artificial insemination except that a woman donor donates an egg. As such, the whole body of legal experience that applies to artificial

insemination by donor will most likely apply to this process as well.

Although one might compare the ovum transfer process to in vitro fertilization or IVF, important differences exist. In vitro fertilization almost always uses the patient's own egg. Ovum transfer always uses a donor egg. Both processes have a choice of sperm, but most often use husband's sperm. Both processes provide a pregnancy experience. With IVF fertilization takes place in a laboratory dish; with ovum transfer, it occurs in a woman's body.

IVF involves anesthesia and a surgical procedure, or at least insertion of a long needle through the woman's abdomen into the ovary to pick up the egg. Ovum transfer requires no anesthesia and is nonsurgical. The principal drawback to ovum transfer is that it requires a third-party egg donor. The use of a third-party egg donor has been cause for concerned legal and moral examination.

The biology of nonsurgical ovum transfer is now well understood. Ovum transfers have been performed in over 14 mammalian species including baboons.

We had prepared a video tape to show you today, a real live transfer that was shown today. However, for technical reasons we were unable to show it to you today. I hope that later on we will be able to show you that tape. It got lost in the mail. We don't know where it was lost.

Mr. GORE. We are sensitive about that at the Science and Technology Committee.

Dr. BUSTER. I can imagine that.

We began work at UCLA in 1979. The scientific team prepared a detailed protocol. An indepth legal study was performed by the Family Law Department at UCLA School of Law.

In early 1980, we contacted a representative of the National Institute of Child Health and Human Development concerning the possibility of NIH funding of this clinical protocol. We were told unofficially that no Federal funds were presently available for this type of work and that they did not expect them to become available in the foreseeable future. We were advised not to apply.

The Institutional Review Board at the Harbor-UCLA Medical Center included fellow scientists, social workers, a lawyer, and a theologian. In July 1981, the protocol was approved. Subsequently the Institutional Review Board worked closely with us to develop appropriate consent forms and to build safeguards to protect all the participants.

In January 1982 the contract was funded and our work began. In January 1982 we began to screen potential donors and infertile recipient couples. All potential participants were carefully examined using an extensive array of medical, psychological, and genetic tests. I tell you, quite frankly, those tests would embarrass the astronauts. We were very careful as to who was involved in this work.

Following additional development of the uterine instruments required to recover the ova, the first completely nonsurgical human ovum transfer was performed in March 1983. We reported this to the scientific community in a letter to the *Lancet* a month later.

[Slide.]

Dr. BUSTER. By the conclusion of the contract in March 1984, we had performed 25 ovum transfers with 4 resulting pregnancies. Two resulted in normal term babies; the third intrauterine pregnancy aborted spontaneously; the fourth pregnancy implanted in a previously damaged fallopian tube and was surgically removed. The birth of the first baby was reported in a letter to the editor in the February 17 issue of the Journal of the American Medical Association.

[Slide.]

Dr. BUSTER. Pictures of the first child appeared in newspapers from Los Angeles to Peking.

The excitement of ovum transfer is the opportunity for fertility it provides for couples who are otherwise destined to be childless. There are several indications for ovum transfer.

Let me stop for a second and show you something else, and I will go into it.

[Slide.]

Dr. BUSTER. This is a real live fertilized ovum. This is called a blastocyst, and I want to show it to you because it is awesome what you are looking at. This embryo contains perhaps 100 cells. It is a round ball and inside of it, which is hard to show from where I am here, but you can see a little finger sticking out into this hollow ball from about, oh, 2 to 4 o'clock. That structure is called the innercell mass, and it is that mass of cells that become that baby that you saw on the front page of the Los Angeles Times and in the Peking newspapers.

I think it is just awesome that these cells know precisely where to go to make a human being possible.

[Slide.]

Dr. BUSTER. This second slide is another blastocyst that became the second child. Here the innercell mass is more toward the middle of the ovum. It does not stick out from the side, as you saw the previous one, but it is still the same incredibly wondrous structure.

[Slide.]

Dr. BUSTER. This slide goes back to something more mundane, the indications for ovum transfer. The first indication, as I mentioned, is untreatable obstructive tubal disease.

A second indication is ovarian failure, a condition in which a woman has no eggs. Such a woman can now be treated with the ovum transfer since a donated egg is used.

A third indication for ovum transfer is maternal genetic afflictions in which the woman does not wish to pass on her disease to her children. By using a donated egg, such women can bear children without fear of transmission of their genetic abnormality.

The fourth indication is for those women whose ovaries are inaccessible for in vitro fertilization. These women may also now have children by these processes. These women previously considered hopeless for IVF now have an alternative.

Finally, women whose infertility is unexplained may sometimes be treated by the ovum transfer process.

The ethical, moral, and legal issues of ovum transfer are of interest to this subcommittee. They are also of interest to us.

As we carefully look at these issues, we see concerns that are common to all medical care, risk-benefit ratios, appropriate informed consent, liability, appropriate indications for the procedure, and when performance researched the ethics of human experimentation.

We also see certain issues that are common to all advanced techniques in human reproduction, the time that life begins and sanctity of family are all of great concern to us. Neither of these issues is unique to the ovum transfer process.

Our review of these matters with our Institutional Review Board, our UCLA legal consultant and other interested and caring people has caused us to conclude that this process and technique is basically one which can bring great benefit and happiness to many couples who would otherwise be unable or unwilling to have children. This process is pro-life and it is pro-family.

You will notice there is some risk from this procedure to the donors. This risk can be explained thoroughly and the donor can have unlimited time to consider risk and the benefit before making an informed choice. Each of our donors have been strong supporters of the program.

Thank you for your attention.

I would next like to introduce to my right Mrs. Cindy Imhof. Cindy Imhof, I think, has far more understanding and is far more authoritative in speaking about the donor process because Cindy has been working in the research program as a donor.

Cindy Imhof.

[The prepared statement of John E. Buster follows:]

PREPARED STATEMENT OF JOHN E. BUSTER

Mr. Chairman, Ladies and Gentlemen, my name is John E. Buster. I am a Professor of Obstetrics and Gynecology at the UCLA School of Medicine at the Harbor Hospital Campus in Torrance, California.

Earlier this year our team at the Harbor-UCLA Medical Center announced the birth of two healthy children to each of two women who had been infertile. The process utilized to start these two pregnancies was nonsurgical human ovum transfer, a technique developed by our group through a research contract financed through private funds. Six months later, the families are supremely delighted with these beautiful children, and we are looking forward to offering this new technique to the many infertile women who will benefit from it.

The purpose of my presentation is to introduce the members of the Subcommittee to the technology of the nonsurgical human ovum transfer process, the safeguards we have implemented, and the moral, legal, and ethical issues that surround the work.

The ovum transfer process is a technique offered to infertile women whose infertility is due to untreatable disease of the fallopian tubes. It uses an egg donated by another woman. It is performed in five steps. In our program, this was done by having a number of spontaneously ovulating donors and recipients who could give and receive each others eggs. The second step is to inseminate the fertile donor with semen from the husband of the infertile patient. Conception takes place in the body of the donor. The third step, lavage or washing out of the uterus of the donor, takes place 5 days later. Recovery of the fertilized egg is possible because it is free floating in the donor's uterus. This is a virtually painless office procedure that takes about 5 minutes. The fourth step is to recover the fertilized ovum in the lavage fluid. The fifth step is to transfer the fertilized ovum into the uterus of the infertile recipient. This also is simple and painless. If all goes well the fertilized ovum attaches to the wall of the infertile woman's uterus, and 9 months later the woman gives birth to a child that is fathered by her husband but arises from a donated egg.

Although, one might compare the ovum transfer process to in vitro fertilization or IVF, important differences exist. In vitro fertilization almost always uses the patient's own egg. Ovum transfer always uses a donor egg. Both processes have a

choice of sperm, but most often use husband's sperm. Both processes provide a pregnancy experience. With IVF fertilization takes place in a laboratory dish; with ovum transfer it occurs in a woman's body. IVF involves anesthesia and a surgical procedure or at least insertion of a long needle through the woman's abdomen into the ovary. Ovum transfer requires no anesthesia and is nonsurgical. The principle drawback to ovum transfer is that it requires a third party egg donor. The use of a third party egg donor have been cause for concerned legal and moral examination. The biology of nonsurgical ovum transfer is now well understood. Ovum transfers have been performed in over 14 mammalian species including baboons.

We began work at UCLA in 1979. The scientific team prepared a detailed protocol. An indepth legal study was performed by the Family Law Department at UCLA School of Law. In early 1980 we contacted a representative of the National Institute of Child Health and Human Development concerning the possibility of NIH funding of this clinical protocol. We were told unofficially that no federal funds were presently available for this type of work and that they did not expect them to become available in the foreseeable future. We were advised not to apply.

The Institutional Review Board at the Harbo-UCLA Medical Center included fellow scientists, social workers, a lawyer, and a theologian. In July 1981 the protocol was approved. Subsequently the Institutional Review Board worked closely with us to develop appropriate consent forms and to build safeguards to protect all the participants. In January 1982 the contract was funded and our work began. In January 1982 we began to screen potential donors and infertile recipient couples. All potential participants were carefully examined using an extensive array of medical, psychological and genetic tests. Following additional development of the uterine instruments required to recover the ova the first completely nonsurgical human ovum transfer was performed in March 1983. We reported this to the scientific community in a letter to the *Lancet* a month later.

By the conclusion of the contract in March 1984 we had performed 25 ovum transfers with four resulting pregnancies. Two resulted in normal term babies; the third intrauterine pregnancy aborted spontaneously; the fourth pregnancy implanted in a previously damaged fallopian tube and was surgically removed. The birth of the first baby was reported in a letter to the editor in the February 17th issue of the *Journal of the American Medical Association*. Pictures of the first child appeared in newspapers from Los Angeles to Peking.

The excitement of ovum transfer is the opportunity for fertility it provides for couples who are otherwise destined to be childless. There are several indications for ovum transfer.

Mr. GORE. Dr. Buster, thank you for your statement, and we are pleased to have you, Mrs. Imhof, and we invite you to proceed at this time.

Ms. IMHOF. Good morning.

I read an article in a paper 2½ years ago that said, "Help an infertile woman have a child." At that time I was divorced and I had a 7-year-old-son, and I really didn't think that I would ever have any more children of my own. So I gave the hospital a call and made arrangements for the interview.

When I showed up for the interview, a lovely woman, Suzanne Spira, interviewed me and she said, "Why are you here answering that ad? I am really curious." And all I did was hold up a picture of my son, and I figured that if I can help another woman have a child that is as healthy as my child and be as happy having a child and being a mother, then why not help her since I just have these glorious eggs, and I should donate them.

I come from an extremely healthy background. I have two 90-year-old grandmothers. I have no cancer, no diabetes, disfigurements, or any type of catastrophic diseases, and I figured that I should just have someone else use these genes since I wouldn't be using them. So after I had this quite extensive physical and psychological test and meetings with psychiatrists and with doctors, I finally was approved to go into the program.

Since the program is so convenient, all I have to do is have my hormone level monitored 4 or 5 days during the month to see when my hormone peak is, then they would know when to inseminate me, and then come back, which is only withdrawing blood which takes maybe 5 minutes, or not even that.

Mr. GORE. That is the hormone check?

Ms. IMHOF. Yes. And then to go back for the lavage which takes another 5 minutes. It is completely painless. You can't even tell that you are having it done.

Mr. GORE. That is about 4 or 5 days later?

Ms. IMHOF. Yes, after the egg is fertilized, that I couldn't see why not do something like this. It is very convenient and since my body would normally reject the egg, then why waste the egg?

The funny thing about this is that people have a lot of different reactions about someone in their family participating in a program like this. I am talking about my family. I have gotten extreme encouragement from everyone, especially my 90-year-old grandmother.

But the most enthusiastic is my son, and he has been right there all the time, and it is really kind of funny because every month he will ask me if we are going to make a baby for another lady. We, in parenthesis, I think is cute, and 1 month I told him that no, that we were not synchronized with another woman, and he looked at me and he says, "Well, mommy, you are just wasting your egg." And I thought that was a great way to put it, was that why should anyone waste an egg that another woman that could not have children could use, and that is why I am in the program.

When the first baby was born, it was really a very interesting experience. I was so excited to see that someone else could enjoy being a mother and that I was part of that to help. Now I am not sure if that was my egg or whose egg was used to make the first two children. Right now everything is kept anonymous, but there are only 12 donors and at UCLA, there are 4,000 women right now waiting just at that one area to have children, but none of us knew which one is the actual donor of the egg. But we all felt that we had contributed so much toward perfecting the procedure of making the catheter and everything else, that we felt that we had all helped even though we might not have been the actual donor of the egg.

One of the best things about ovum transfer is that it is done naturally. The donor does not have to take any kind of hormones or anything like that to regulate her cycle, so it is done completely naturally. When the egg is taken out, it is before it is attached to my body, so it has not received any of my blood supply or anything like that. So when it is placed into the other woman, she is the one that will give the blood supply and the oxygen and have the egg grow inside of her.

And I feel that any woman that carries the child and nurtures it and the environment that she places herself in while she is pregnant and actually delivers the child and hopefully nurses the child and raises the child, then I feel she is the mother. All I did was donate an egg that God placed in my body, and I am just thankful that it is a very healthy egg that I could donate, so I feel that she is the real mother.

I think that these children that are going to be born from this program are very special because I know I am donating this egg completely out of love, not out of necessity like someone that might have to give up a child for adoption. So if in 20 years or so, I get a knock on the door and this child wants to meet his genetic mother, I would more than welcome it because just to see that the child became healthy, that is all I would want to see. I wouldn't have any feeling that that was my child per se. It might be mine genetically, but the people that raise the child and everything, that is the real mother and the real parent.

I really want to give my thanks to the foundation that provided the funds to do this research. I think that this whole program is so incredible, and I really am enthusiastic and happy that I could participate in it.

Thank you very much.

[The prepared statement of Cynthia Imhof follows:]

OVUM TRANSFER

Two and a half years ago I read an article that said "Help an infertile woman have a baby". At that time I was divorced with a 7 year old son and knew I probably would not have any more children of my own. I called Harbor-UCLA Hospital to make an appointment for an interview. The first question asked was why did I respond to the ad. My reply was just to hold up a picture of my son.

I come from an extremely healthy background without cancer, diabetics, disfigurements or catastrophic diseases, therefore I couldn't see why I should just waste these wonderful genes I was blessed with. After a complete physical, genetic workup, psychological test, interviews with a psychiatrist and finally Drs. Marshall and Buster, I was accepted into the program.

Since this program takes so little of my time and is completely painless, I have been more than willing to go through the process every month. My only regret is that I will be 36 this month and can no longer donate my eggs.

If you're wondering about the reactions I receive when I tell people what I'm doing, everyone is thrilled that I can be involved in such a fantastic program. My son is probably the most enthusiastic. One month he asked if "we" were going to make a baby for another lady. When I answered no because there wasn't a match, he stood there and said "But Mommie, you're just wasting your egg!" It could not have been said any better. Why should any woman waste her eggs when there are so many women who desperately want children and cannot conceive?

I can hardly explain the emotional change in my life thinking that I can give the ultimate gift to another woman so she too can experience all the wonders of being a mother.

When the first baby was born, I think we all felt it really didn't matter who's egg they used because each of us helped to make the baby by assisting the doctors perfect catheter.

One of the best things about Ovum Transfer is that it is done naturally. The donor just goes through her regular cycle to produce an egg, is artificially inseminated then, 4 or 5 days later, has the lavage done to extract the fertilized egg. The egg is then placed in the recipient within hours. The egg is removed before that donor even knows she's conceived because her body will not go through any noticeable changes.

This is the next best thing to the natural way because the woman can actually carry her husband's child and she did not even have to undergo any surgery. This wonderful process opens a door for so many woman who either cannot conceive or are afraid of passing on a birth defect or genetic disease.

These children will be very special because it has taken three people's love to make them. The donor just contributes an egg that God placed there. The woman who carries, nourishes, delivers and raises the child is the "real" mother. If in 20 years I receive a knock on the door—I would be pleased because I have given the egg out of love not necessity. I would feel more like a Godmother to the child than a mother.

I give my thanks to the foundation that provided the funds to help Harbor-UCLA Hospital do the necessary research to perfect this incredible advancement in the Medical Field.

BIOGRAPHY

CYNTHIA (CYNDY) IMHOF.—The youngest daughter of a family of three children and 4th generation native Californian. My father is President of a multimillion dollar distribution company. I have a college degree in accounting and presently have the position of Operations Analysis for a West Coast Division of a large conglomerate. I have received numerous awards in both school and work. My most recent was "ABNER" which means Above, Beyond Normal Employee Responsibility. I also hold two beauty contest titles. I have recently remarried and have a 9 year old son.

Mr. GORE. Well, Thank you. We are happy that you could participate in this hearing today and give us your unique perspective. We have several questions, but we will hold off until we hear the rest of the panel.

I would like to call now on Mrs. Barbara Brooks who is at the center of the witness table with her son, Daniel. Mrs. Brooks, we are delighted that you could join us today. As I mentioned a moment ago, you have given birth to Daniel after he was conceived in vitro and as your physician told us, you are the oldest mother to give birth to an in vitro child, and that is a distinction that I know that is unique. And let me invite you to proceed with your statement in the hopes that you can help us attain the proper perspective when we look at these issues. Please proceed.

Ms. BROOKS. Thank you, Congressman. Needless to say, this is a bit of a surprise. I had not anticipated this at all. My statement will speak for itself.

Mr. GORE. Well, your prepared, typed statement will be included in full in the record at this point, and then you can say whatever you like.

Ms. BROOKS. May I read it?

Mr. GORE. Sure, if you want to do that.

Ms. BROOKS. I was rather distressed last night after viewing the evening news. It seems to me people are developing tunnel vision. They are seeing only the possible abuses that could result from in vitro programs and few, if any, of the positive uses.

I strongly agree that there is a need for guidelines in this area in an attempt to prevent the abuse of technology. But I even more strongly disagree that legislation is the place to begin. It is simply impossible to legislate away abuses of technology. As long as technology exists, there will be people determined to abuse it who will not be deterred or regulated by legislation. The setting up of a national advisory board to explore the issues and make recommendations, some of which may lead to legislation, seems a much more rational way to proceed.

I understand I am the oldest woman ever to deliver an in vitro baby. I am pleased to share with you our son, Daniel, who is 4 months old as a reminder of one of the wonderful results of an in vitro program. One does not have to look far into the medical records of those of us whose only opportunity to have children rests with in vitro programs and other alternatives, including donor egg and donor sperm, to see that the children who result from these

procedures are wanted children. Daniel was wanted more than words can say, and we love him with all our hearts. He has already brought us more joy than we could ever have thought possible. He is a healthy, happy baby. But there are a large number of parents in this world who were not, and will not be, as lucky as we. They have, or will have, the tremendous misfortune to have children with genetic birth defects. I would hate to see us lose sight of the rare opportunities in vitro programs, in particular provide for learning more about these defects and, as a result, learning how to prevent many of them.

We are concerned about making this world a better place in which to live. Helping to produce a healthier population seems to me to be a contribution that is an opportunity of a lifetime.

Mr. GORE. Thank you very much. We will have some questions in just a moment.

Let me say that I think that what you are reacting to is the English initiative in Great Britain and to create a regulatory agency that will require all doctors and scientists to be licensed in this area. That is not what we are proposing and not what these hearings are aimed toward. We are essentially in agreement with you, that a national commission to stimulate a dialog on the biological implications of these issues and possibly to make implications for legislative steps as they appear to be necessary.

Ms. BROOKS. This is in response to the news media last night.

Mr. GORE. Which, in turn, covered in part 2 British—

Ms. BROOKS. They seemed to be saying a lot of legislation was needed; I disagreed. That is why I prepared the statement to hand to you this morning.

Mr. GORE. We will pursue it in questions. I want to defend them to the extent that I don't think they were advocating anything, just reporting on what was happening in England.

Ms. BROOKS. I hope not. Thank you.

Mr. GORE. Let me now introduce our next witness, Dr. Richard Marrs, from the Women's Hospital in Los Angeles, CA, accompanied by Mrs. Diana Bassi. Dr. Marrs has been a pioneer in the cryopreservation or frozen embryo technique, and we are delighted to have you join us today, Dr. Marrs, and we look forward to your testimony.

Dr. MARRS. Thank you.

I would also like to thank you and the subcommittee for the opportunity to discuss our procedures and our future plans.

In vitro fertilization is a process that we have utilized at our institution since September 1981. We were the second program in the United States to establish this process and delivered the third child in North America in June 1982.

You have heard from previous testimony the basic steps of the in vitro fertilization process and our program is very similar in many respects. Since the beginning of our clinical work, our primary focus has been investigation of stimulation profiles to optimize follicle development and oocyte number as well as oocyte quality.

The second area has been the improvement of fertilization success and embryo quality in the laboratory setting. Our most recent area of research is investigating the use of cryotechniques for freezing and storage of the human embryo for subsequent utilization

and replacement back to the egg donor's uterus. It is these areas that I wish to direct my comments to you this morning.

First of all, stimulation of the ovulatory female has proven to be a somewhat difficult but an extremely interesting area of investigation. Since 1981, we have utilized many different stimulatory agents to maximize ovarian response during the treatment cycle for in vitro fertilization procedures.

We found early on that clomiphene citrate, which is a drug that we commonly use as a single agent, produces an average of two to three eggs per patient cycle which allowed on the average two embryos to be available for placement during that cycle.

In subsequent studies, utilizing combinations of clomiphene citrate and most recently human menopausal gonadotropin, we saw again an increase in the number of eggs retrieved and the number of embryos placed.

We then utilized therapy with the tropins and saw we were able to increase the number of eggs to over five eggs per patient per treatment cycle and that gives us an average of almost three embryos replaced per cycle.

Our final method and our current method to stimulation includes a combination of clomiphene and pergonal concurrently, and we see now an average between four and five viable oocytes collected with a resultant average of over three embryos produced in a treatment cycle.

It is important to reflect on the ability to produce multiple eggs because that certainly increased our pregnancy success in the past 18 months. For instance, if only a single embryo is available for replacement during the treatment cycle, our clinical pregnancy rate averages around 12 percent of patients that receive a single embryo placed. On the other hand, if we have three or four embryos replaced, the clinical pregnancy rate increases to approximately 30 percent per replacement cycle.

With the ability to produce multiple eggs and multiple embryos, we are also seeing more and more of an increasing risk of multiple gestation, multiple pregnancies. The risk overall in our patient population of twins is approximately 15 percent of replacement cycles when the patient receives three or four embryos. If we look at the incidence of triplets, the incidence is between 3 and 5 percent in our patient population.

As we discussed yesterday, triplets are a major obstetrical problem, both to the infants as well as to the mother, and that is certainly something that we attempt to avoid even though in our program, as well as the other major centers around the world, an increasing risk of triplet gestation is occurring.

However, as the laboratory aspects, for instance, the culture conditions in the laboratory where we are harboring the embryos, improved, we may see even more of an increasing risk of multiple gestations occurring with multiple embryo replacements. It was, therefore, important for us to look at a technique to utilize these extra embryos, such as that when they did develop after stimulation, we would have an alternative method so that these embryos could be utilized in the patients that produced them.

Embryo freezing technologies seemed to be a logical step to take as we saw a number of eggs and number of embryos increasing.

Embryo cryopreservation and storage has been utilized for many years in the cattle industry. There are major experimental studies that have been reported looking at the results and outcome of bovine embryo freezing.

Overall, in the cattle industry today, with frozen embryos that are stored and then thawed and ultimately transferred, the calving rate of approximately 50 percent is what is expected as the norm.

In our laboratories, we initiated our experimental studies, looking at the embryo cryopreservation with the mouse system. In several sets of experiments, we used different sets of freezing and thawing in over 800 animal embryos. The results of these studies demonstrated overall about a 70-percent recovery rate of embryos that were frozen. They appeared morphologically normal after thawing and continued to grow and ultimately develop blastocysts and then ultimately hatch.

We also looked at the effect of freezing on chromosome material. We used different methods, both karyotyping as well as methods to determine whether toxicity had occurred to the DNA component. We found that in our various types of freezing and thawing, we saw no increased incidence of sister chromatid exchange activity, which is a marker of DNA toxicity, compared to a controlled population which was unfrozen.

We also showed that there was no increase in chromosome aberration, chromosome breakage, or chromosome deletion in the cryopreservation techniques utilized. It was after these studies that we approached our institution review board and ethics committee with protocols for the use of cryopreservation techniques in the human.

These procedural systems have been utilized in our human in vitro fertilization activity since 1981 and even before that time. Anything that we do in our human in vitro program is reviewed by the institutional review board, both at the University of Southern California as well as a separate review board at the Hospital of the Good Samaritan in Los Angeles. These two bodies must approve anything that we institute as a change in our basic system or any new activity that we hope to utilize.

Since approval, we have been utilizing the cryopreservation system in patients that produce embryos in excess of three or four that will be utilized for replacement during the treatment cycle. In those patients that produce extra or excess embryos, the embryos are frozen and stored.

To date, we have stored between 40 and 50 embryos and of these, 18 have been thawed at this point in time. Twelve patients have received a total of 16 embryos, 13 of which appeared to be of excellent quality. At the present time, the first nine patients that have received the embryo replacement with the frozen-thawed embryo have not demonstrated evidence of pregnancy. Currently three patients are awaiting results of their replacement cycle.

The only other program currently involving human IVF research that is utilizing embryo cryopreservation is the program in Melbourne, Australia. They currently have reported two live births following replacement of frozen stored embryos. There is no indication of any abnormality in any of the pregnancies that have been established.

If embryos which are produced by IVF are cryopreserved for variable time periods, several theoretical advantages become evident. Because ovarian hyperstimulation is currently utilized for in vitro procedures, the hormonal milieu may not be conducive in a significant number of patients. However, if embryos are cryopreserved and then transferred when the patient is in a spontaneous ovulatory cycle, implantation may occur more frequently.

Moreover, if embryo replacement is not done during the recovery cycle, the embryo can be allowed to develop to a more advanced stage either before or after cryopreservation, and, therefore, a determination of a viable preimplantation embryo is more readily made.

More importantly, the occurrence of implantation may increase when the embryo has developed to a preimplantation stage of development rather than a rate seen with the replacement of a four or eight-cell embryo.

Other positive aspects of embryo cryopreservation include the decrease in the number of treatment cycles necessary for pregnancy occurrence and, therefore, a decrease in the financial cost per pregnancy. Overall, as in any other area of scientific investigation and research, it is always important to remember that through the use of various investigative methods as you see outlined here in a very controlled fashion with a group of individuals that oversees and looks at our results on a frequent basis—the Institutional Review Boards—good scientific research can be performed.

The fear of the public for rampant or noncontrolled experimentation on human life is something that should not happen today. The Institutional Review Boards at the hospitals or research medical centers very definitely legislate and control the activities of the investigators within those systems. It is only individuals that utilize technology outside of the established norm will there be loss of control.

Currently, the two major societies in our specialty of obstetrics and gynecology are establishing guidelines and recommendations and review boards for reviewing activities of the physicians that perform in vitro fertilization. Both the American College of Obstetrics and Gynecology and the American Fertility Society are involved in formulating guidelines presently.

More specifically, the American Fertility Society is now formulating a special interest group for the study of human in vitro fertilization and embryo replacement. This special interest group will be a governing board which will draw guidelines and recommendations and also will hopefully provide a review committee which will consist of scientists as well as lay people to look at the ethics and the legality of the in vitro technology as it advances.

It is through the combined efforts of these types of societies and individuals that we can safely proceed in the very sensitive issues of human reproductive functions.

The discussions yesterday focused on the issues such as embryo rights, the ownership rights to the embryo and the use of embryo splitting. These questions need to be addressed in a realistic way and guidelines need to be established. These guidelines cannot be established by a purely legislative body just as they cannot be put forth by a pure scientific organization. There has to be a mixture of

scientific, legislative, theologic, legal, and public interaction when these norms are established.

It is only with this multifaceted approach that these very significant ethical, moral and scientific issues can be addressed. It would be my sincere desire that guidelines concerning these issues would take into account not only the rights of the embryo but the rights of the patients that we treat.

In all the advancements in reproductive technology we currently are utilizing, as well as the ones which are sure to come, we must never lose sight of the fact that we deal with a very vulnerable population of patients. We must protect the physician/patient relationship and provide a medically safe and emotionally supportive environment as we attempt to provide them their strongest desire, a child of their own.

Thank you very much.

[The prepared statement of Richard P. Marrs follows:]

HUMAN IN VITRO FERTILIZATION --
STATE OF THE ART

Richard P. Marrs, M.D.

Introduction

Mammalian reproduction has been studied for many years in various animal systems and many attempts to extrapolate this information to the human reproductive system have been undertaken. However, because of species differences full detailed knowledge of human replication is still lacking. In animals, direct visualization of extracorporeal gamete fertilization, embryo development, and gestation ultimately led to application of this technique to human reproduction. After many years of trials with in vitro fertilization procedures, Edwards and Steptoe produced the first human offspring in 1978. Since that time the human in vitro fertilization and embryo replacement (IVF-ER) process has been modified, refined and improved. Presently, IVF-ER not only provides the infertile couple with the hope of producing a child of their own but it also provides the investigator with a "physiologic window" through which a dynamic view of human reproduction can be studied and understood.

Initially, IVF-ER was designed to provide a mechanism for women to reproduce who had no fallopian tube function. IVF-ER was merely a mechanism to bypass the fallopian tube. However, with increased success and knowledge, other infertility factors are now treated by this process.

Currently candidates for IVF-ER include not only patients with tubal disease, but also patients with male factor infertility as well as couples with idiopathic or unexplained infertility. Although IVF-ER has not replaced conventional forms of infertility therapy, this procedure should be utilized when conventional methods have not resulted in a successful outcome. It is expected in the future, as pregnancy success increases, that IVF-ER will replace many of the conventional surgical therapies currently utilized to attempt to treat reproductive failure.

Technical Aspects of IVF-ER

The evolution of extracorporeal fertilization in the human has been rapid. Initially, stimulated ovarian cycles were utilized by Edwards and Steptoe but this method was discontinued because no pregnancies resulted. As the use of oocyte recovery during a spontaneous ovulatory cycle resulted in the first human in vitro pregnancy in 1978, investigators in the field utilized the spontaneous cycling female. Timing of oocyte recovery was performed by utilization of ultrasound (U/S) estradiol (E_2) measurement and luteinizing hormone (LH) determination. Daily measurements were performed to measure the rise of preovulatory E_2 levels and as the dominant follicle approached 18 mm in diameter urinary LH measurements were performed every 3-4 hours to identify the initiation of the preovulatory LH increase. Laparoscopy for oocyte collection was performed 26 to 28 hours from the initiation of the LH increase. In 1980 Irounson et al. utilized clomiphene citrate 150 mg, days 5 through 9 and demonstrated a pregnancy establishment from multiple embryo transfer in 9 of 103 treatment cycles. Thereafter, IVF teams world-wide began utilizing some form of ovarian stimulation prior to oocyte recovery.

Ovarian Stimulation Methods

Various regimens of ovarian stimulation have been utilized to induce multiple follicle development for the purpose of in vitro fertilization. The dominant follicle selection theory in the primate seems to demonstrate a need for exogenous ovarian stimulation to occur early in the cycle if multiple dominant follicles are to be generated.

In the past two years, we have studied various regimens of ovarian stimulation. Initially clomiphene citrate, 150 mg daily for five days was utilized as a primary method for ovarian stimulation. Since studies in the primate indicated that dominant follicle selection occurred early in the cycle, an initial study was performed utilizing clomiphene citrate at various times in the cycle to determine if multiple follicle development could be more successful if early initiation was utilized. Clomiphene 150 mg/day was initiated beginning day 3, 4, 5 or 7 of the menstrual cycle. It was seen in this group of patients that the number of follicles generated, oocytes collected, fertilized and embryos transferred per cycle were optimal when clomiphene was initiated on day 5. Significant decreases in the number of eggs collected, fertilized and the number of embryos transferred occurred when day 3, 4 and 7 were utilized for clomiphene initiation (Fig. 1, 2). These data were somewhat divergent from what was expected from studies in the primate model, however, when the day 3 clomiphene group was looked at more closely, it appeared that early in the treatment cycle •ultrasound demonstrated multiple follicle development but as follicle growth continued, the majority of these follicles did not continue to develop. Therefore, we performed a second study utilizing combinations of

clomiphene citrate and human menopausal gonadotropin (HMG) to determine if a prolonged stimulation cycle would result in larger numbers of multiple follicles. In this study the patients received either clomiphene citrate 150 mg from day 3 through 7 (Group I) or clomiphene citrate 150 mg (day 3 through 7) followed by 2 ampules of HMG daily thereafter until 2 follicles, 18 mm or greater, were visualized by ultrasound at which time HMG was discontinued (Group II). A third group of patients received clomiphene citrate 150 mg (day 3 through 7) combined with HMG, 2 ampules/day administered day 3, 5 and 7 of the cycle and daily thereafter until follicle sizes reach 18 mm. The fourth group of patients received 2 ampules of HMG beginning day 3 of the cycle and this was continued until two follicles were visualized that were 18 mm or greater. In all groups E_2 concentrations were followed until a plateau occurred when hCG was administered. Results of this study revealed that the patients receiving clomiphene citrate followed by HMG or clomiphene citrate combined with HMG had optimal numbers of follicle development, oocyte recovery rates, fertilization and embryo transfer rates (Fig. 3, 4). The HMG stimulated group had a lower oocyte recovery rate and lower embryo transfer rate which was thought to be due to an overstimulation of the follicle causing difficulty in retrieving eggs secondary to thick, luteinized follicular fluid. Moreover, immature oocytes were recovered which were difficult to fertilize in vitro. Of interest, there was a significant increase in spontaneous endogenous LH release prior to administration of hCG in this group of HMG stimulated patients.

Beginning in 1983, two regimens of ovarian stimulation were primarily utilized in our center. Clomiphene citrate 150 mg followed by HMG 2

ampules per day was utilized in approximately half the patients treated. HMG was administered until 2 follicles, 18 mm or greater were visualized and then estradiol measurements were continued until a plateau occurred and hCG was then administered. The remainder of the patients received a modified HMG treatment. Three ampules of HMG given daily beginning day 3 of the cycle and continued until 2 follicles 15 mm or greater were visualized. Thereafter when the E_2 plateau occurred hCG was administered and laparoscopy was performed 36 hours later. In the group receiving HMG, an average of 5.5 ± 0.4 oocytes were recovered per laparoscopy of which 3.6 ± 0.4 fertilized and ultimately 2.8 ± 0.2 embryos were transferred per cycle. In the group receiving clomiphene 150 mg followed by HMG 3.3 ± 0.2 oocytes were retrieved per follicle aspiration cycle, 2.5 ± 0.2 fertilized and 2.3 ± 0.2 embryos were transferred. There was no significant difference between these results. In comparison to these types of stimulation, patients receiving only clomiphene 150 mg, had fewer oocytes recovered, fertilized and embryos transferred (2.7 ± 0.3 , 2.2 ± 0.1 and 2.0 ± 0.1 respectively) which was significantly less than the combination treatment or HMG alone (Table 1).

Currently, a modification of the combination therapy is being utilized. Clomiphene citrate 100 mg per day is given day 3 through 7 concurrently with 1 ampule of HMG. HMG is continued at a dosage of 1 ampule daily until 2 follicles of 18 mm or greater are seen on ultrasound. hCG is administered when E_2 plateau occurs. Thus far in treatment cycles with this regimen, 4.3 ± 0.3 oocytes have been collected per cycle by laparoscopy of which 3.7 ± 0.3 have been fertilized and 3.1 ± 0.3 embryos transferred per cycle. Pregnancy rates with the various stimulation

methods have shown an increasing trend. Pregnancy rates with clomiphene citrate alone resulted in pregnancy in 12% of laparoscopy cycles. The combination of clomiphene citrate followed by HMG resulted in 21% pregnancy initiation per laparoscopy, whereas 20% of HMG stimulated cycles that went to laparoscopy resulted in pregnancy. The combination of clomiphene citrate and Pergonal have to date produced a pregnancy rate of 26% per laparoscopy.

Monitoring Ovarian Response

When utilizing the stimulated ovarian cycle, judgement of optimal response is of prime importance. Measurement of follicle size by real time ultrasound has been shown to correlate well with hormonal parameters of follicular growth in spontaneous and stimulated ovarian cycles. To determine precise timing of oocyte/follicle maturation for IVF-ER, it is best to utilize a combination of ovarian ultrasound scanning, daily peripheral estradiol (E_2) measurement and luteinizing hormone determination (Fig. 5). Initially ultrasound determines the number and size of follicles developing after stimulation (Figure 6) and this is correlated with E_2 secretion. In clomiphene citrate and HMG combination regimens, HMG is continued after the initial five days of clomiphene administration until two or more follicles are ≥ 18 mm diameter. After discontinuation of HMG an ovulatory dose of human chorionic gonadotropin (hCG), 4,000 IU is administered when E_2 levels plateau and 36 hours later laparoscopic aspiration is performed. The same basic approach is followed for HMG induced follicle growth except the medication is discontinued when 2 or more follicles reach or exceed 15 mm diameter and hCG is administered as E_2 levels plateau. LH

measurements are performed to insure that endogenous LH release has not occurred prior to hCG administration thus necessitating an earlier oocyte recovery time.

Oocyte Recovery

From the initiation of human IVF procedures, the laparoscope has been the primary instrument utilized for oocyte collection. In our program we utilize an offset or operating laparoscope, as this allows the surgeon an extra operating channel in cases where severe adhesions are encountered. A secondary puncture site is utilized suprapubically in the midline for placement of a grasping instrument to stabilize the ovaries during follicle aspiration. A third puncture site is placed midline for the small sleeve through which the needle aspirator is placed. We use the teflon-lined needle aspiration system which is connected to a constant suction source adjusted to 100 to 140 mm Hg negative pressure. Under direct visualization the aspirating needle is placed into the follicle and as the needle enters the follicle wall the suction is begun. The needle is removed after follicle collapse is visualized and the needle is then flushed with 0.5 ml of Hepes medium. With the use of this system and no follicle washing or flushing, oocytes are collected in approximately 90% of follicles aspirated (Table 2). If an oocyte is not obtained in the follicle aspirate, a heparinized Hepes solution can be instilled through the aspiration needle after reintroduction into the follicle and rinsing of the follicle can be performed. This may allow oocyte recovery in the follicles that the oocyte is not obtained in the original aspirate.

Recently several European centers have reported the use of ultrasound directed aspiration. The advantage to this technique is that it does not necessitate a general anesthesia. Moreover, it is optimal for patients with severe pelvic-abdominal adhesions since entrance to the follicle occurs from the interface between the follicle wall and the bladder wall thus abdominal access is not necessary. In the reports thus far, oocyte recovery per follicle ranges between 50 to 75% and complications such as hematuria, or intra-abdominal bleeding are negligible. Even with multiple puncture sites through the bladder, no urinary tract damage or complications have been reported. If this oocyte recovery rate is confirmed by other centers, the ultrasound directed aspiration technique may replace the use of laparoscopy for oocyte collection.

Oocyte-Embryo Culture System

A rigidly controlled, strictly defined laboratory environment must be maintained for successful in vitro fertilization and embryo growth. Over the years various tissue culture media have been utilized for oocyte culture but the most commonly used medium is Ham's F-10. Fresh Ham's medium is prepared weekly as detailed in Table 3. Prior to use for human gamete culturing, the medium is tested with mouse embryos to determine normal growth promoting properties. Only medium which demonstrates a hatching rate of greater than 70% of mouse blastocysts after 96 hours of culture, is utilized in the human culture system.

The Ham's medium is supplemented with heat inactivated (56°C v 30 minutes), millipore-filtered patient serum which is collected immediately

prior to hCG administration. The serum is added in a 10% concentration to the insemination plates and after the first 18-24 hours of culture the embryos are transferred to media with 20% human serum for further growth.

Culture conditions are extremely important and the culture environment must be rigidly controlled. Different centers utilize various containers for oocyte culturing. In a study performed at our institution, oocyte fertilization rates were significantly increased when culturing was carried out in organ culture plates rather than tissue culture tubes (Fig. 8). The egg is placed in a 90% nitrogen, 5% oxygen and 5% carbon dioxide atmosphere at a temperature of 37°C and 100% humidity. Some centers utilize a 5% carbon dioxide and air atmosphere with good success.

Of equal importance to the culture environment is the determination of oocyte maturity at the time of recovery. Fertilization rates have increased from 40% to 80-90% in the past two years partially because of increased knowledge in identifying oocyte maturation. Immature oocytes are often recovered during stimulated cycles and must mature prior to fertilization attempts. Immature oocytes either fail to fertilize or undergo polyspermic fertilization. A morphologic grading system has been established and utilized. With pre-incubation of immature oocytes (for as long as 36 hours) a higher fertilization rate is obtained (Fig. 8). The oocytes are identified in the follicular aspirate by viewing aliquots of the follicular fluid with a dissecting microscope at 6X magnification. Once identified, the oocyte can be inspected with a higher magnification (40 to 400X) inverted head phase contrast microscope to try to morphologically stage the maturity. Once the stage of maturity is determined, the oocyte

is placed into an organ culture plate and incubated with Ham's F10 and 10% serum for variable periods of time prior to sperm addition. With this variable pre-incubation schedule an increase in fertilization success has been demonstrated with immature oocytes (Fig. 10).

Sperm Preparation and Insemination

In cases where the male is thought to be normal (i. e. normal semen analysis) a routine semen culture is done prior to initiating a treatment cycle. If bacterial growth is present in the sperm, antibiotic treatment utilizing Vibramycin 100 mg Bid for 4 to 6 weeks prior to performing IVF.

In males with normal semen profiles a standard 2 step washing procedure is performed. A 0.5 ml aliquot of fresh semen obtained by masturbation is mixed with 3 ml Ham's medium and centrifuged at 300 XG for 10 minutes. The supernatant is removed and the sperm pellet is resuspended in 2 ml Ham's and centrifuged at 300 XG for 10 minutes. The supernatant is again removed and the sperm pellet is resuspended in 1 ml of Ham's and is incubated for 2 to 6 hours. Prior to addition of spermatozoa to the oocyte culture dish, the supernatant is removed and a precise count and motility determination is performed on a 0.1 ml aliquot of the sample. Thereafter 50 million motile cells are added to each oocyte culture dish (Fig. 10).

If IVF is being performed for an abnormality in the semen analysis, screening with the hamster penetration assay is utilized. It appears that observation of penetration in the hamster assay correlates fairly well in the IVF system. If penetration rates are decreased below the normal

fertile range (<15%) treatment of the ejaculate to improve spermatozoa quality is attempted. The three primary methods utilized to improve penetration ability are albumin gradient separation, "swim up" separation or Percoll gradient separation. These washing techniques are described in Figures 11, 12 and 13. The improvement in sperm penetrating ability seems to be greatest with Percoll separation (Table 4). If a male responds with an improvement of sperm penetration of zona free Hamster eggs with one of these methods then that method is utilized during the IVF treatment cycle. If a male has a zero penetration rate on two separate hamster penetration tests, then an IVF procedure would not be recommended unless donor semen was acceptable to the couple. However, because so few spermatozoa are necessary for successful fertilization in vitro, many oligozoospermic males can produce pregnancies now with the IVF-ER process. Fertilization rates in our program range from 63% in males producing less than 10 million spermatozoa to 86% in males producing more than 10 million spermatozoa.

Embryo Culturing

Once spermatozoa are placed into the oocyte culture dish an 18 hour co-incubation time is utilized. Thereafter the corona cells are gently removed from the egg by dissection with 28 gauge needles under the dissecting microscope and visualization with the dissecting microscope of male and female pronuclear formation signifies fertilization (Fig. 14). Multiple pronuclei signify polyspermic (Fig. 15) fertilization and these oocytes may begin normal cleavage and thus an abnormal fertilization process may not be detected unless visualization takes place 18 hours after fertilization. If the fertilization process is completed normally, oocytes are transferred

into Ham's F10 with 20% serum, cultured for an additional 24 hours at which time they are inspected and then placed back into the uterine cavity at a 2 to 8 cell stage of development (Fig. 16, 17). Embryos that show evidence of fragmentation (Fig. 18) or polyspermic fertilization are not replaced into the woman's uterus.

Embryo Replacement

Cleaving embryos are placed into the uterine cavity by a transcervical approach. The patient is brought into the operating room adjacent to the embryo culture laboratory and placed in a lithotomy position and the replacement of the embryo(s) is performed with a side-hole teflon catheter. Embryo(s) are loaded into the catheter in 30 ml of the patient's serum and then dispelled after the catheter is placed in the region of the uterine fundus. No anesthetics are required for this part of the procedure and the patients are maintained in a slight Trendelenburg position for 6 hours prior to returning home.

Pregnancy Success

A steady increase in successful outcome with IVF-ER has been observed in the past few years. Prior to the use of stimulated cycles pregnancy success was approximately 3 to 12%. With the use of the stimulated cycle pregnancy rates in 1983 ranged between 15 to 25% of patients laparoscoped. One factor that appears to affect pregnancy occurrence is the number of embryos replaced (Table 5). There is a significant improvement in outcome

when two or more embryos are replaced. Spontaneous abortions appear to occur somewhat more frequently with 20 to 40% of pregnancies being lost after there is evidence of pregnancy establishment. Biochemical pregnancies have been reported from all centers. These are defined by a detectable low level increase of b-hCG 14 days after embryo replacement and a delay of menses. Menstrual bleeding ensues and disappearance of hCG occurs. Biochemical pregnancies have been reported to occur between 10 to 30% of pregnancies. As laboratory parameters have improved there appears to be an increasing incidence of survival of multiple gestations (twins, triplets and quadruplets) thus necessitating a re-evaluation of the optimal number of embryos replaced during an IVF-ER cycle. Currently, we replace a maximum of three or four embryos in order to minimize the risk of multiple gestation. The use of progesterone to support the luteal phase is utilized in some centers, however, pregnancy outcome does not appear to be affected with or without progesterone usage.

Future Considerations

Factors which possibly affect pregnancy incidence in the IVF process include the number of embryos replaced, stage of the embryo(s) at the time of replacement, the overall quality of the embryo and the receptivity of the endometrium at the time of replacement. Moreover, the quality of the luteal phase during a stimulated cycle may be less likely to promote pregnancy initiation or maintenance than a natural cycle.

One method that can be utilized to avoid these many problem areas is embryo cryopreservation and storage. Animal data certainly support the

successful use of embryo cryopreservation for breeding purposes and from this experience cryopreservation techniques may be utilized in the human.

In our laboratory several studies have been undertaken to determine the effects of freezing and thawing on normal embryonic development. The animal model utilized in these experiments was mouse embryos. The first parameters that were compared was the use of a rapid versus a slow freezing process. Mouse embryos at the eight cell stage were frozen in plastic straws through a programmed controlled freezing process beginning at room temperature at 1°C per minute increments to 0° degrees where at this point dimethylsulfoxide (DMSO) was added in three equal parts at 10 minute intervals to make a final concentration of 1.5 molar (M) DMSO solution. DMSO acts as a cryoprotectant for the cells as the freezing-cooling process is performed. From 0° degrees down to -7° a rate of 1° per minute was utilized. At -7°C (approximate freezing point of 1.5 DMSO) manual seeding was performed and cooling was reinitiated at 0.33°C per minute down to -45°C . At this point approximately half the embryos were plunged into liquid nitrogen and stored (rapid freeze group). Upon thawing these embryos were taken from the liquid nitrogen chamber and placed in 37° water bath for rapid thawing. The remainder of the original embryos were continued to be cooled at 1°C per minute from -45°C down to -75°C and then placed directly into liquid nitrogen. This was considered our slow-freeze method. At the time of thawing these embryos were thawed slowly at room temperature and the DMSO was slowly diluted out of the culture by simple dilutions with Ham's F-10 media over a 30 minute interval in both groups (Table 6).

In the slow-freeze process of 335 embryos frozen 238 of these embryos (71%) appeared morphologically normal after thawing. Ninety-seven of the original embryos that were frozen evidenced normal growth and morphological characteristics. In comparison, the quick freeze thaw protocol demonstrated again good survival after the freezing thawing process. In this group 335 embryos were frozen and thawed and of those 283 (82%) demonstrated degeneration. Overall after 24 hours, 235 or 68.1% of the original embryos frozen and thawed demonstrated normal growth parameters and normal morphology.

The second phase of this study included the determination of chromosomal damage or DNA toxicity. Sister chromatid exchange rate is a sensitive marker that has been utilized in our laboratory for several years to determine potentially toxic effects to the DNA material housed within the nucleus of the cells of the embryos. This method was utilized to determine any adverse effect of this freezing-thawing process on these embryos that were studied. In the control group of 52 embryos (non-frozen embryos) a mean SCE rate of 20.4 ± 0.4 was demonstrated. In the slow freezing process, a mean of 21.3 ± 0.6 (54 embryos) demonstrated no significant difference from the control population that remained unfrozen. Likewise the rapid freeze-thaw method demonstrated a similar SCE rate of 20.3 ± 0.5 . Overall with freezing, storing, thawing, there was no evidence of DNA toxicity that would be related to the process of embryo freezing. Similarly, we looked at the incidence of chromosomal aberration; the incidence of chromosomal deletion or chromosomal breakage, and it was shown that in all three groups there was not statistical difference in chromosomal aberrations in any of three groups. The incidence of

chromosomal aberration in the control population was 6.1% and the slow freeze group is 3.8% and the quick freeze group was 4.8%. Therefore, in our studies up this point there has been no evidence that freezing a cleaving embryo demonstrated any potentially toxic or harmful properties to the embryo itself. Moreover a recovery rate of approximately 70% of embryos frozen is certainly in a range of acceptability in this type of system.

Following the completion of this and other studies, the request for use of human embryo cryopreservation was made to the Institutional Review Boards at the University of Southern California and the Hospital of the Good Samaritan and after fulfilling all of the requirements of these committees, (Appendix 1) freezing and storage of human embryos was initiated. The determination to store an embryo in any individual patient came about after discussion with the patient and after determination that three or four viable embryos were present to be utilized for a replacement procedure during that treatment cycle. If patients had embryos in excess of these numbers, then these embryos (if normally cleaving) were frozen with the slow freezing thawing method. To date, approximately 40-50 human embryos have been frozen and are being stored in our liquid nitrogen chambers. Since the initiation of this program, 12 patients have returned for an attempt at pregnancy with thawed embryo transfer. The first nine patients that have received an embryo transfer have not become pregnant. All of these patients received one embryo at the time of replacement. Currently, three patients are pending outcome of their frozen embryo replacement cycle. These three individuals have received two embryos at the time of replacement.

recovery rate after thawing the human embryos has been good with 13 of 18 (72%) embryos demonstrating normal morphology after thawing. Dr. Alan Trounson in Melbourne, Australia has reported several clinical pregnancies which have been established with this method of human embryo freezing, storage and transfer. To date two live births have resulted from the replacement of frozen-thawed embryos. To date there has been no abnormalities in the clinical pregnancies that have been established and the two babies that have been delivered have been normal by all parameters.

If embryos which are produced by IVF are cryopreserved for variable time periods several theoretical advantages become evident. Because ovarian hyperstimulation is primarily utilized for IVF-ER the hormonal or endocrine milieu may not be conducive to implantation in a large number of patients. However, if embryos are cryopreserved and then transferred when the patient is in a spontaneous ovulatory cycle, implantation may occur more frequently. Moreover, if embryo replacement is not done during the recovery cycle, the embryo can be allowed to develop to an advanced stage either before or after cryopreservation and therefore a determination of a viable pre-implantation embryo is more readily made. More importantly, the occurrence of implantation may increase when the embryo has developed to a pre-implantation stage of development than with replacement of 4 to 8 cell embryos.

Other positive aspects of embryo cryopreservation include the decrease in the number of treatment cycles necessary for pregnancy occurrence and therefore a decrease in the financial cost per pregnancy. Moreover, as

technology advances and improved methods of gene identification for removal or replacement become available, the knowledge of cryobiology in regards to embryo storage will be vital. In the future, with appropriate genetic markers, preimplantation genetic screening can be performed and hereditary genetic disorders may be significantly reduced or even totally eradicated. Embryo cryopreservation may play a large role in these areas. Even though embryo cryopreservation has theoretical advantages, clinical trials are necessary to demonstrate the real clinical benefit in the human IVF-ER process at the present time.

In summary, the technique of IVF-ER is in its infancy. The knowledge that is being compiled will allow even greater advances in the future. The use of gene splicing and DNA probes to eradicate various types of hereditary diseases will become reality.

Even though ethical and moral controversies have been raised in the past and most certainly will be raised in the future with IVF-ER, the underlying factor which will continue to interest investigators in this area of research, is the eradication of human infertility and inherited disease and the advancement of knowledge in human reproductive function.

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Table 1. Comparison of Stimulation Regimens

Type	# Oocytes	# Fert	# Trans
CC 150	2.7 ± 0.3	2.0 ± 0.1	2.0 ± 0.1
CC 150 ± HMG	3.3 ± 0.2	2.5 ± 0.2	2.3 ± 0.2
HMG	5.5 ± 0.4	3.6 ± 0.4	2.8 ± 0.2
CC 100 & HMG	4.3 ± 0.3	3.7 ± 0.3	3.1 ± 0.3

Table 2. LSC Results (Constant Suction)

Patient Group	(N)	Number of Follicles	Number of Oocytes	Vol/Follicle (cc)
Tubal Disease	26	78	62 (79%)	6.5 ± 0.04
Idiopathic Infertility	8	21	18 (86%)	6.7 ± 0.1
Male Factor	2	5	3 (60%)	7.0 ± 0.5

Table 3. Media Preparation

I. Stock Solution

- A. One package of powdered Ham's F-10 with glutamine is dissolved in 250 ml of twice distilled water.
- B. Penicillin G 75 mg/liter, and streptomycin 50 mg/liter are added.

II. Culture Media

- A. 62.5 ml of stock solution is added to 187.5 ml of twice distilled water (250 ml volume).
- B. Calcium lactate 61.3 mg, sodium bicarbonate 420.1 mg, and potassium bicarbonate 126.9 mg, are added.
- C. Osmolarity is adjusted to 280 mOsm.
- D. pH is adjusted to 7.3-7.4.
- E. Media are filtered by 0.22 μ filters and stored refrigerated in sterile 17 x 100 snap top tubes.
-

Table 4. Comparison of Separation Techniques

	Sperm Recovery	Motility Enhancement	Hamster Penetration
Two Step Wash	66% ($p<0.01$)	46% ($p<0.01$)	Unchanged
"Swim Up"	26%	79%	Unchanged
Albumin	40%	92%	Unchanged
Percoll	35%	88%	Improved ($p<0.005$)

TABLE 5. CLINICAL PREGNANCY RATES BASED ON
NUMBERS OF EMBRYOS REPLACED

# EMBRYOS	# CLINICAL PREGNANCIES
1	2/27 (12%)
2	5/27 (19%)
3	8/31 (26%)
4	5/17 (29%)

TABLE 6

FREEZING PROTOCOLS

8 CELL EMBRYOS IN HAM'S F-10 + 20% SERUM
(0.2 ml Volume in Plastic Straws)

COOL @ 1°C/MIN
TO 0°C

ADD DMSO IN 3 EQUAL PARTS AT 10 MIN INTERVALS
TO MAKE 1.5% CONCENTRATION

COOL @ 1°C/MIN
TO -7°C

SEED STRAWS

COOL @ 0.3°C/MIN

AT -45°C

PLUNGE TO LIQUID
NITROGEN
(QUICK-FREEZE)

THAW IN 37° WATER BATH

COOL @ 1°C/MIN

AT -75°C PLUNGE TO
LIQUID NITROGEN
(SLOW FREEZE)

THAW AT ROOM TEMPERATURE

CURRICULUM VITAE

Richard P. Marrs, M.D.

<u>BORN:</u>	December 6, 1947 Paducah, Texas														
<u>MARITAL STATUS:</u>	Married, 1 child														
<u>EDUCATION:</u>	<table border="0"> <tr> <td>1962 - 1966</td> <td>Tivy High School Kerrville, Texas</td> </tr> <tr> <td>1966 - 1968</td> <td>Junior College, Schreiner Institute, Kerrville, Texas</td> </tr> <tr> <td>1968 - 1970</td> <td>University of Texas, Austin, Texas, B.A.</td> </tr> <tr> <td>1970 - 1974</td> <td>University of Texas Medical Branch, Galveston, Texas, M.D.</td> </tr> <tr> <td>1974 - 1976</td> <td>Residency, Obstetrics and Gynecology, University of Texas Medical Branch, Galveston Texas</td> </tr> <tr> <td>1976 - 1977</td> <td>Chief Resident, Obstetrics and Gynecology, University of Texas Medical Branch, Galveston, Texas</td> </tr> <tr> <td>1977 - 1979</td> <td>Fellowship in Reproductive Endocrinology, University of Southern California School of Medicine, Los Angeles, California</td> </tr> </table>	1962 - 1966	Tivy High School Kerrville, Texas	1966 - 1968	Junior College, Schreiner Institute, Kerrville, Texas	1968 - 1970	University of Texas, Austin, Texas, B.A.	1970 - 1974	University of Texas Medical Branch, Galveston, Texas, M.D.	1974 - 1976	Residency, Obstetrics and Gynecology, University of Texas Medical Branch, Galveston Texas	1976 - 1977	Chief Resident, Obstetrics and Gynecology, University of Texas Medical Branch, Galveston, Texas	1977 - 1979	Fellowship in Reproductive Endocrinology, University of Southern California School of Medicine, Los Angeles, California
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1976 - 1977	Chief Resident, Obstetrics and Gynecology, University of Texas Medical Branch, Galveston, Texas														
1977 - 1979	Fellowship in Reproductive Endocrinology, University of Southern California School of Medicine, Los Angeles, California														
<u>CERTIFICATION:</u>	February, 1980, American Board of Obstetricians and Gynecologists December, 1983, Sub-Specialty Boards, Repro- ductive Endocrinology, American Board of Obst- etrics and Gynecology														
<u>LICENSURE:</u>	State of Texas, 1974 State of California, 1977														

<u>FACULTY APPOINTMENTS:</u>	1977 - 1979	Clinical Instructor, Department of Obstetrics and Gynecology, Los Angeles County-University of Southern California School of Medicine, Los Angeles, California
	1979 - 1982	Assistant Clinical Professor, University of Texas Medical Branch, Galveston, Texas Assistant Professor, Section of Endocrinology and Infertility, Department of Obstetrics and Gynecology, Los Angeles County-University of Southern California School of Medicine, Los Angeles, California
	1982 - present	Associate Professor, Section of Endocrinology and Infertility, Department of Obstetrics and Gynecology, Los Angeles County-University of Southern California School of Medicine, Los Angeles, California

PROFESSIONAL MEMBERSHIPS:

Local	Willard R. Cook Ob/Gyn Society Los Angeles Ob/Gyn Society Salerni Collegium
National	American College of Obstetricians and Gynecologists -Fellow American Fertility Society American Medical Association Pacific Coast Fertility Society Society for Gynecologic Investigation Endocrine Society Society for the Study of Reproduction

HONORS AND AWARDS:

1966 - 1968	Scholarship to Schreiner Institute
1978 - 1979	Jeanne Kempner Fellowship Award
10/21/79	Squibb Prize Paper Award, "Identification of PRL Secreting Pituitary Adenoma by TRH Stimulation". Pacific Coast Fertility Society.
5/80	Scientific Exhibit Award, "Clinical and Laboratory Monitoring Methods Used in Human Menopausal Gonadotropin Therapy". American College of Obstetricians and Gynecologists Meeting.
1980	Senior Residents Award for Excellence in Teaching
10/19/82	Memorial Foundation Award Thesis, "Clinical Application of Techniques used in Human In Vitro Fertilization Research. 49th Annual meeting of the Pacific Coast Obstetrical and Gynecological Society.

COMMITTEES

Chairman, In Vitro Fertilization Special Interest Group
 Ad Hoc Committee, American Fertility Society
 Outpatient Surgery Committee, Hospital of the Good Samaritan

EDITORIAL REVIEW BOARDS

Fertility and Sterility
 Journal of In Vitro Fertilization and Embryo Transfer

Mr. GORE. Thank you very much.

Our final witness on this panel is Mrs. Diana Bassi who was, to our knowledge, after checking extensively, the first woman in this country to receive a frozen embryo, and I believe that was in May of this year, and I don't want to jump ahead to your testimony, Mrs. Bassi. I want to welcome you and invite you to proceed. You can switch seats if you like.

Ms. BASSI. Good morning, Mr. Chairman.

I am a free-lance interior designer, and my husband is a sound engineer in the film industry.

Mr. GORE. Excuse me. It would help if you could bend the neck of that microphone down a little bit and it will pick up your voice a little better.

Ms. BASSI. I am a free-lance interior designer, and my husband is a sound engineer in the film industry.

In 1970 my gynecologist ordered oral contraceptives for corrective measures. In 1972, I was plagued by a persistent bleeding problem and developed serious infections in my ovaries and fallopian tubes. This was treated with antibiotics; however, the antibiotics didn't work at the time, and a second opinion was to get a hysterectomy. I was only at the age of 21 and I did not feel I wanted a hysterectomy.

A second physician was consulted, and he recommended that I use more antibiotics. In spite of this treatment, I still have repeated problems, yeast and bladder infections, to this day.

Since the oral contraceptions were creating adverse side effects, my doctor stopped them in 1976. In 1978, I had surgery for an ectopic pregnancy on the left side. In 1979, I took clomed, which is a fertility drug, in an attempt to become pregnant again. Six months later, I became pregnant and suffered a second ectopic pregnancy.

After my first one, I did have the normal tests, the tests to prove that my tube was open, and yet I still had another ectopic pregnancy. At that time, during surgery, a part of my fallopian tube was salvaged for further reconstructive surgery. It was at that time that I was referred to Dr. Marrs.

After the first laparoscope by Dr. Marrs, prognosis was that my chances for becoming pregnant on my own were very slight. It was at that time and in view of his findings that it was decided to try the in vitro program, which we had discussed in our first consultation.

Since early 1981, I have had four laparoscopes. In September 1981, five eggs were retrieved, and one was transferred. In July 1982, four eggs were retrieved and three were transferred. In May 1983, on the 16th day, I had an LH surge, which basically meant I ovulated, and again the same thing happened in July 1983, only on the 13th day.

In November 1983, five eggs were retrieved, three were transferred and two of them were frozen, and on May 4, the frozen embryo was transferred, and one of them had disintegrated.

During the years Dr. Marrs' research, knowledge and techniques in the in vitro program have expanded and improved immensely. He has strengthened and improved every aspect of the program. Along with his continuing knowledge and improved techniques will

come greater success and greater reward, hopefully successful implants.

Along with this, however, the cost to the patient has increased immensely. Most patients have little or no insurance coverage in all the areas of the procedure. It is my belief that the insurance companies must come to understand the need for such coverage. Presently it costs approximately \$5,000 to go through each completed cycle.

I believe it is necessary for the insurance companies to take part in the in vitro program so they can help everyone in need of this, and it just doesn't happen for those that can afford it. There is a great need for this.

Today there are approximately 300,000 childless couples in the United States. However, there are only 70 IVF centers that are located primarily in the highest population areas. As a result, there is a long waiting list at each clinic which forces many couples undue delay in beginning the program.

Frank and I feel very fortunate that we are able to participate in the in vitro program. It offers our only chance to have a child. Personally, I will pursue this program as long as I am able or until pregnancy does occur. The opportunity to use the frozen embryos as well as the immediate transferred ones offers to us as patients a greater chance of pregnancy occurring.

In addition, it does cut down on the number of surgeries by giving us two or more chances with each individual surgery. In the in vitro fertilization program, it does not tamper with DNA nor does it experiment with genetic makeup. It simply provides the opportunity through which a wife's fertile ova can be fertilized by her husband's sperm and maintained in the environment where it will be later transferred into its biological mother.

To be prepared for the unexpected situations where either a wife, husband or both may be incapacitated or diseased, the University of Southern California has chosen to give their IVF patients three choices for the disposition of the frozen embryo.

One, donate any frozen embryo to another infertile couple or; two, to use the frozen embryos for research purposes. Three, thaw the frozen embryos and discard them.

Frank and I have chosen all three options. If another couple might benefit, we desire Dr. Marrs to use our frozen embryos for their purposes. Should he feel that any of the frozen embryos may be helpful in his research, we have granted him permission to use them for that purpose.

However, should he feel that any are of no value, he is to discard them in the standard manner. Nevertheless, we believe these frozen embryos are our property and, as such, we hold the option to make any decision we deem fitting for any given situation or occasion.

In this exciting new age of advancing medical technology, Frank and I feel very grateful to have the opportunity to have these options available which are very special to us. Hopefully, the in vitro program will result in a normal pregnancy for us with all of its resulting joys and wonders.

Mr. GORE. Thank you very much. I appreciate the statements that all of you have given.

Let me begin now with some questions with you, Ms. Bassi. Let me ask you, first of all, when did you receive the frozen embryo?

Ms. BASSI. I believe it was May 4, 1983.

Mr. GORE. Now, you and your husband are still trying for a successful pregnancy, is that correct?

Ms. BASSI. Correct.

Mr. GORE. Now, did you have any special feelings about the fact that this embryo was frozen before implantation? You had previously tried to become pregnant with the normal in vitro fertilization procedure that did not include the freezing of the embryo.

Ms. BASSI. Correct.

Mr. GORE. When the doctor told you that this embryo was frozen and was going to be implanted, what went through your mind at that time?

Ms. BASSI. I hoped that it would work this time only for the reasons stated earlier, there were no drugs in my system. My system was completely clean. It had been 4 or 5 months since my last in vitro try, and I felt very comfortable that maybe it would work this time. I had no objections to the egg being frozen at all.

Mr. GORE. I think that is an important perspective because all of the questions that we discuss here about the ethical problems with freezing embryos and what you do with the extras and all that, in your mind, none of that really occurred to you at all?

Ms. BASSI. It doesn't at the time.

Mr. GORE. You want to be pregnant?

Ms. BASSI. Exactly.

Mr. GORE. And your doctor told you that this offered a greater chance for you to successfully become pregnant, and that is really the only thing that mattered to you?

Ms. BASSI. It still is the only thing that matters. I will continue to freeze any extra because he has had a good recovery rate on me. He usually recovers around five eggs, and if they all do fertilize and he doesn't implant them all, I don't want to just discard them. I do want something done with the ones that aren't implanted immediately.

Mr. GORE. Now, the extras that have been created, you said you have chosen all three of the options given to donate to another couple, the second was to have them destroyed, and the third was to allow Dr. Marrs to use them in research.

When you and your husband talked with Dr. Marrs about the research, was that a difficult decision or a relatively easy one for you?

Ms. BASSI. They were all relatively easy. Whatever I have gone through, I want to help someone else. If it ultimately doesn't work for me, I want this to make it easier for someone else, and I feel Dr. Marrs can benefit from using anything that he has learned from me for someone else.

Mr. GORE. Now, I have tried to set what I believe is the proper context for this next question, and to put it in proper perspective, but I want to hear it in your words. You know that many people are very troubled by the use of these extra frozen embryos for research and for experiments even though they are designed to find out great new advances in science. What do you say to the people who are troubled by those experiments?

Ms. BASSI. I don't know that I have an answer for that really. They have to know the program. They have to want a child as much as my husband and I do. When you are in our situation, we don't see bad things happening with these frozen embryos. We want a child. This is one way that we can have one or our only way other than adoption, and I don't know.

It is hard for me to understand some of the things that we have heard here today and yesterday because in our situation, we look at what we want, and it is a child, and this just offers us a way to do it, and I hope nothing will stop that in what has come out in the last couple of days.

Mr. GORE. Let me ask you, Ms. Brooks, to join the conversation at this point. Your basic point in the statement that you showed me this morning when you came to the hearing room, your basic point is, and correct me if I am wrong, that you can put all of these difficult, subtle and very sensitive bioethical questions on one side of the scale, and if they are being pursued and addressed in a responsible way, you believe that the joy and happiness that results from the successful outcome of these procedures just completely outweighs the difficulty and the dilemmas and the rest? That is essentially what you are telling us, isn't it?

Ms. BROOKS. Yes, it is. The key word I think is "responsible." You used the key words, "pursued in a responsible way." Those of us who were here yesterday applaud your efforts to set up an advisory board which seems to be the outcome, as you had stated earlier from your proceedings.

We just feel that this is incredibly important. I think that when these concepts were originally introduced, I don't know that we had any way of imagining the various possibilities, the options, the complications. It is a very complex issue, and I don't think that there was any way to really foresee that originally.

But I feel so strongly, I have Dan here in my arms, but, as I say, how could we have known? He is wonderful.

Mr. GORE. He came in right on cue there.

Ms. BROOKS. Yes, he certainly did.

Yes, but since I am 41, adoption wasn't a viable alternative. Everybody we applied to said, "You are too old." We didn't know that we had a problem until I was 36, and a lot of agencies don't allow you to apply for adoption after the age of 35. It just never occurred to us, and Dan, and I are in the 15-percent normal infertile range or category. So, yes, you said it better than I could have.

Ms. BASSI. If I may say one thing about the adoption, we have also applied to all the agencies, and their requirement is you have to be under 36 before you apply, but it was pointed out that the girls are having children today are 14 years old. To some one at 14, 32 is ancient. They don't want their children to go to parents that are as old as 32 years old.

Mr. GORE. Well, I think it is interesting that both of you actively tried to adopt children before using these techniques.

Ms. BASSI. We didn't try before. In Los Angeles it takes 4 or 5 years before the county will even see you through your first appointment. So we have a long wait ahead of us to even be seen if we go through the county. Otherwise, we go through a doctor or a

lawyer and pay astronomical fees for a child, which the insurance won't cover.

Mr. GORE. I understand.

Ms. BROOKS. May I add something here?

Mr. GORE. Sure.

Ms. BROOKS. The only reason we applied for adoption was we never heard of in vitro. We didn't know that was an option open to us. It happened very inadvertently, and we got in very quickly because of my age and because Norfolk felt that they really could help us since I have all of my female organs and my husband has everything. We are functioning. We just weren't getting pregnant.

Mr. GORE. One of the reasons I raised that question is that some of the adoption groups in the United States have expressed the concern that the wider use of these technologies will have an unfavorable impact on adoptions when there are so many children who need to be adopted.

Ms. BASSI. There aren't children that need to be adopted.

Ms. BROOKS. It depends on race and age.

Ms. BASSI. Out of the Caucasian race, there are no children to be adopted.

Mr. GORE. That opens up a whole new area that we are not going to explore, which is one reason we didn't ask them to testify, but I did want them to testify and note for the record that both of you had explored that adoption.

One other thing. Anyone who has wanted children and then finally had children knows the great joy involved.

You, as a representative of parents who are in that 15 percent and who have tried for a long time to have children, and then you finally achieved success with Daniel, is there any way you can put into words exactly what that means to you?

Ms. BROOKS. All I can do is encourage people to keep at it. Keep pursuing the alternatives. There are more of them that become available as technology is better refined and just no matter how many failures you feel you are experiencing or you actually are experiencing, just keep at it.

Mr. GORE. And, of course, Daniel is more eloquent than any words that you or I could choose.

Ms. Imhof, let me ask you a couple of questions. You were the first donor in this country of an egg fertilized inside your body. Since that time, you have donated a fertilized egg every month over a period.

Ms. IMHOF. I don't know that for sure. I don't find out.

Mr. GORE. You have conceived every month?

Ms. IMHOF. Well, I have tried. I have tried as many times as there has been another woman that is synchronized with me. It hasn't worked out every month.

Mr. GORE. Well, the implantation has not worked out every month. Every month you have tried to conceive. How many months has she conceived in a row, Dr. Buster?

Dr. BUSTER. Mr. Gore, she actually does not know how many times. We don't disclose that.

Mr. GORE. I see. That is part of the information policy.

You say that your family and friends have been very supportive of this, and you recount the conversation that you had with your 7-

year-old son. Have you also encountered people who are uncomfortable about what you are doing?

Ms. IMHOFF. Not really. A couple of women have just said, "Well, gee, I am not sure I could do that personally," but everyone says, "Gee, I admire you for being able to do that." But I don't know why. I don't feel like I am anything out of the extraordinary. I am just a regular woman that has a lovely son, and I would like to make someone else happy and have another baby.

So I really don't think that it takes a special person to donate an egg. Maybe just a caring person. I don't know.

Mr. GORE. Dr. Buster, who is the mother? That is a legal term, I guess, but how do you know the answer to that question? Who is the mother?

Dr. BUSTER. I can answer your question in two parts. When I talk to the lawyers, they say they don't know. When I talk to the women about this, they say that the woman who takes on the biological risk, the woman who nurtures and shapes a child for 9 months and gives birth to the child, that is the mother.

I think that any logical thinking human being would recognize that that is the case. Because, indeed, almost all of the biological risk does go with the recipient woman who carries the child and gives birth to it.

Mr. GORE. What do you think about surrogate mothers, the regular surrogate motherhood program?

Dr. BUSTER. The elegance of our process is that the woman who gives birth to the child is the one who raises it, so there is no separation involved at all.

With the surrogate mothering that separation does occur. Women who live with a pregnancy for 9 months, pregnancy, when the child was removed and the breast was secreting and they were normally would be breast feeding the child, the child is taken away. That is a very unnatural event. It is a violation, if you will. It comes with great difficulty.

I don't have a very high opinion of surrogate motherhood personally. It is not my cup of tea, and I wouldn't recommend it to a patient or to a couple.

Mr. GORE. Now, there are different technologies involved here. Yours is different from the procedure that Mrs. Brooks and her husband used in that with your procedure, half of the genes are from outside the marriage.

Dr. BUSTER. That is correct. The pregnancy that results from our process is always from a donated egg. I might add, though, that with the in vitro programs, also where they use donated eggs, the outcome is exactly the same. It is the reverse of artificial insemination, but with our program—

Mr. GORE. But most in vitro programs use the egg from the mother and the sperm from the father, correct?

Dr. BUSTER. That is correct. That is the way it is normally done, but when they have surplus eggs, they do give them away under certain circumstances. Pregnancies have come that way also.

Mr. GORE. But that is a difference from in vitro fertilization, in that half of the genetic makeup of the child is from outside the marriage.

Now, your procedure is different for not only the reason you cited. You avoid that difficult separation, your word was "violent" separation from the surrogate mother.

Also, your procedure gives the social mother experience of pregnancy and gestation and birth, and you have the bonding process which accompanies that, and that is an advantage to your procedure.

Dr. BUSTER. Yes, and finally, the child is that of the woman's husband so she presents to her husband a child that is biologically his.

Mr. GORE. You could use your procedure with donor sperm as well as a donor egg, correct?

Dr. BUSTER. Yes, we could use it that way. That would be akin to a prenatal adoption where all of the genetic material is contributed from outside the marriage. That could be done. In the research program, we feel that it was supremely important that we could remain intact with all of the makings of the family structure, so we used the husband's sperm in all of the cases we have done so far.

Mr. GORE. Do you plan to use donated sperm?

Dr. BUSTER. We have had discussions about that, but we think that the family structure is somewhat disrupted by that, and we don't know quite how to handle that, and we think that needs to be examined by a board and go through protocol to be evaluated and needs prospective analysis of some sort. So we have not done that.

Mr. GORE. Well, I applaud you for taking such care to address the ethical problems, and you went through an extensive examination of these questions before you proceeded with the lavage technique, if I am not mistaken?

Dr. BUSTER. We did, indeed.

Mr. GORE. Now, this English commission, the Warnock Commission, has recommended against the use of your technique at this time, not because of a profound bioethical objection due to the architecture of the relationship, but rather because of concerns about the safety of the embryo.

Do you believe that there is an undue risk to the embryos that are created in your process?

Dr. BUSTER. No, I don't think there is any excess risk at all. Actually, the concern was not for the embryo but for the donor. I think they were concerned about the possibility that injury might occur to the donor.

Mr. GORE. I stand corrected. They don't believe it is safe for the donor?

Dr. BUSTER. Yes, and let me explain that position. First of all, I think you need to appreciate that much of the opinion shaping that took place, in the Warnock Commission, took place before we published our data. In fact, I am astonished that they never even talked to me or any of my team about this. And so when they formed that opinion, they had never even discussed it with us.

At the present time, we have the only experience in the world with this process and have I think an excellent track record of safety to women. I must point out that donors in the program, we have several who give eggs month after month after month very

efficiently. And we find it hard to believe that the process is in any way injurious.

But I must point out that we went to tremendous lengths to perfect these instruments before we ever inseminated a woman in the program. We had to demonstrate that it was painless, we got the fluid back, and that no injury occurred; otherwise our institutional review board would never have let us proceed.

Mr. GORE. I guess I am trying to put into words why I feel uncomfortable about it, and I guess it has to do with the fact that we don't really know what effect there might be on a donor to conceive a child every month and never bring any of those children to term. Isn't it possible that there are some unknown risks here? Well, that question answers itself, but do you think there are some problems that maybe you haven't explored there?

Dr. BUSTER. Yes. First of all, your concern I think, comes from the fact that it is so new and different. And you are kind of going through the same process that we struggled with about 4 years ago. And I don't blame you a bit. There was a reason this didn't happen until 4 years ago, because we were all concerned about the new relationship involved.

We structured the protocol to answer the kinds of questions you are asking about. For example, does a woman who gives an egg each month go through a morning process of some sort? Does she wonder what happened to the child over the years?

We can't answer that question yet, but what we can do is to screen every woman with meticulous care when she comes into a project like this and make certain that she understands and shares that risk with us and then keep track of the women and assess this issue prospectively over time. That is the beauty of doing a thing like this in the program, because we were concerned about that, and we will be able to keep track with women for long periods of time and be able to tell you in 5 or 10 years, or maybe even longer, exactly what the problems are, and deal with them.

Mr. GORE. Now, you say there are certain medical indications where your procedure is, in your opinion, the best one for people to have children.

I want to ask you about the patent question. You are not on the business side of this venture you are engaged in. The people who provided you with funding for your research are the ones who are seeking the patent. And I want to preface my questions with that disclaimer because you are a doctor and a scientist.

Nevertheless, there are medical and scientific values involved, and many people have been highly critical, Dr. Buster, of this effort to obtain patent rights and require payment from anyone else who uses this procedure. It is extremely rare and maybe there is some precedence, but to take a medical procedure that is medically indicated for the treatment of a patient suffering from infertility and claim exclusive rights to that procedure and claim a royalty payment or a license payment from any other doctor that treats his patients with that procedure, that is wrong, isn't it?

Dr. BUSTER. Thank you for prefacing your question the way that you did. I do need to answer your question as a scientist, because in accepting the research fund to this work, we accepted some of the responsibility for the issues that you are talking about. So I will

talk about it in a nonbusiness sense, if I may, to answer your questions and your concerns.

I need to explain a bit about the history of this research program for you to understand how we got where we are.

Mr. GORE. Well, first let me try to short circuit that, if it is not impolite. You sought Government funding and Government funding is widely used for medical procedures and the results are always in the public domain because of a lot of reasons, including timidity and sensitivity of elected and appointed officials to even discuss this area, no funding was available from that source. So you felt forced to go into the private sector to get funding from the private sector.

Now, I take it that part of your justification is that since the Federal Government turned you down and since you were forced to go into the private sector to get the money, therefore, you are justified in following through with the quid pro quo that the source of private financing requested in return for their money? Does that short circuit that?

Dr. BUSTER. That is beautiful. Thank you for your understanding. Indeed, we were turned down by the Federal Government.

Mr. GORE. But does that justify it?

Dr. BUSTER. It does not by itself justify what you said is happening here and what I need to do is explain to you what the patent scientifically really does, and to do that I need to just explain a couple of points about where the money came from because you must understand this. This is critically important to do.

We could not bill the women for this work. The IVF programs can bill the women, and we cannot bill the women. So there indeed was no choice.

Mr. GORE. Now tell me why you couldn't, so I will understand that.

Dr. BUSTER. Because in 1979, 1980, there were no babies from this process. It wasn't known to work. We could not offer a treatment in a research program where the women were subjected to certain risks and ask them to pay for it. There was just no way it could be done. We had to have adequate research funds to make it happen right.

I must point out that if you talk to all the scientists who know about our work, I think you will hear almost no criticism for how it was done. It was done right because we had adequate funds to pay for psychological tests, the consultants, the IRB and all these things. It made it happen the right way, and that is why we are here today with a program that works and people that have no concerns about how the work was done.

So we would agree, and you would understand, that we did have to go for funds. And we were quite unable to find any social capitalists who would give it to us because no one thought this project was really worth it. We had to compete for the same dollars that the oil wells and the gas producers compete for, and those dollars have certain restrictions to them that I want to talk about in more detail now.

I think to answer your question in a very precise way, I have to point out to you what the lawyers have told me that patents do. What they do is to provide the sponsors with a limited control over

their business activity during the early years the company is growing. The return to us as researchers is that they will allow us to disclose in the scientific journals the precise details of what we did. The patent laws require them to disclose fully and completely precisely how the process is done.

I would have had a mutiny in my laboratory if I could not publish every detail of this process in the medical journals with the peer review process. And as every scientist who goes through here will tell you, we did, except for one thing, the details of a catheter which is still a trade secret. That becomes public knowledge once the public has access to it. It will be disclosed to everyone, so they can use it.

Mr. GORE. Well, if they pay you—

Dr. BUSTER. Let me come back to that—that goes to a third party—of what I need to explain to you about why the patents exist. Understand that my research team wouldn't touch this project if they had not been allowed by our sponsors to disclose what may have been trade secrets and never been given publicly to our colleagues. Indeed, we have told the whole thing publicly. I showed you the slide today that we have done that.

Mr. GORE. I understand that and applaud that, and that takes care of one of the scientific values at stake here. But the whole theory of the patent law has been always disclosure in return for exclusive rights for a limited period of time, but in medical technology process are not or have not been patented.

Dr. BUSTER. Now that you understand my last point, and I thank you for doing that, for taking the time to understand it.

Mr. GORE. There may have been some in the past, but it is most unusual.

Go ahead.

Dr. BUSTER. It is unusual. It is new, and I think I must point out to you that in the 1980's, that the way all medical care is being paid for is a lot different than it was, in large part because dollars that were available from Government sources have dried up. And we have been asked to look at new and different ways of paying for our work and for bringing new techniques to the marketplace.

But I want to get right to your question about the royalty business because I know that is what you are concerned about, but I want to make sure where you were before I talked about that.

Those investment dollars came to us with an obligation to see to it that it was paid back and the process that is used to handle investment dollars to pay a royalty on the treatment, the tools, the process, whatever it is. Now, the process issues, the medical procedures issue, is simply a legal thing, the law that I have told you isn't looked at any differently than in a tool or instrument and, in fact, FGR is the company that holds these patent positions, they were able to come up with over 100 patents on medical processes that have already been issued. It was not new to them at all; it was new to me. I did not know about that.

The patent people say that the process patent is nothing more to them than a part of the patent package that they built around these procedures, and they see it in a very dispassionate way. My colleagues see it differently, and, of course, I see it differently, and it makes me uncomfortable to talk about this.

Mr. GORE. A lot of your colleagues are critical of that, aren't they?

Dr. BUSTER. Yes, they are. And we were critical of it too, but as we come to understand it, and then if you come to live in the realities of the 1980's, we don't see it the same way. For one principal reason, we know that the motivation behind our sponsor is not to restrict the technology, it is to make it available to as many physicians and patients as quickly as possible as is compatible with good medical care. The motivation is not to withhold it, but to open it.

Mr. GORE. And make more money from it.

Dr. BUSTER. And the way that they make money from it is through the payment of royalties, which is simply a system for paying back of investment.

Mr. GORE. In fact, you and your sponsors have in mind, and correct me if I am wrong, but I am basing this on a conversation you had with the staff, a national network for matching and synchronizing donors with the recipients and having embryos flown from city to city where and when they are needed on a nationwide basis and making a rather large business out of it. That is what you have in mind, isn't it?

Dr. BUSTER. They do have plans like that. What I have in mind is to be a scientist and do my research work.

Mr. GORE. That is what your business partners have in mind?

Dr. BUSTER. This is what our sponsors have in mind. I must point out to you also what our relationship with them is. They have paid for a research project by a grant through UCLA. That is how we are tied with them. So to make it clear, this is the kind of plan that they have in mind, and it does sound like a big business because it is a lot of work that needs to be done. A lot of women out there want those babies.

Mr. GORE. Let me ask you, if we have thousands of half brothers and half sisters out there as a result of the wider use of this technology, does that concern you about the genetic risks posed by that? This becomes more common, and you have lots and lots of people who are siblings but don't know it.

If there are intermarriages, is that a trivial question, or is it one that is deserving of serious consideration?

Dr. BUSTER. It is a serious question because we all wonder about that. We all know there are medical problems that come with marriages between relatives. It was already a problem before we got involved with this because in your State and mine there are many people who are related and don't know it because the father is unknown. It is already a problem. But to deal with it specifically, here the number of embryos that would drop into the country nationwide is really very small and the dilutional effect of population spreading them all over the country, say 5 or 10 or 15 per woman, would be a trivial problem.

There is a way of managing it. If you tell the children from where they came, it is possible to tell with blood tests that a potential marriage partner is not related to them.

Mr. GORE. Professor Cafrin recommended in his testimony yesterday that for children born with this technique who are told, there should be established and maintained a national data bank

that could be referenced in the event the problem arose. Is that something you would agree with?

Dr. BUSTER. I think that is a wonderful idea. One of the reasons for looking upon this as a fairly sizable business activity is because that becomes possible. We think the way it should be handled is that the donors and couples having the children should be contacted each year and should disclose to one another what has happened to each other. The women who all donors want to know because it affects the child that comes from their genes and the couples with the children want to know because it may affect their medical history as well.

It is a very serious matter and I think needs to be addressed in a very organized way.

Mr. GORE. Dr. Marrs, let me ask you, do you feel uncomfortable by the prospect of Dr. Buster's corporate venture with these donated embryos being flown around the country and on a very large scale?

Dr. MARRS. I think you increase the risk of the problem arising. I think everybody discussed yesterday and what we are discussing today, we are looking at ways to minimize risks from the procedures that we are currently utilizing and the procedures that we are going to utilize in the future. If there is a large-scale embryo donation process, I think there needs to be very well-kept records so that siblings know who their respective siblings are, so I think it can be controlled and it can be recorded and you can utilize a well-structured data system.

As far as the corporate structure, we faced the same problems as did any in vitro program anywhere in the world, the European programs, the Australian programs, for the programs in the United States. There was no funding available. We essentially started our program with our own money. We personally bought equipment. We personally had donations from individuals that were interested, but it was money that we set up to provide a process to the patient.

Our first 25 or 30 patients essentially had no charge made to them. We accepted no fees and provided no professional services as far as moneys brought into the university. So there are ways to avoid any type of big business intervention in scientific research even today, even though Federal money is not available. So there is nothing that has been patented in IVF research from the beginning in England until now. So there are alternatives and corporate intervention does bother me when you are talking about medical procedures.

I don't think we can be governed by big business just like we can't be totally governed by a legislative body. You have to proceed with the scientific work that we are interested in.

Mr. GORE. Are you uncomfortable with obtaining a process patent on the Lavage procedure?

Dr. MARRS. You can patent equipment, devices. All of those things have been done. I think when you step into the realm of patenting a procedure that a physician performs then you are dealing with a much different animal. I think if that begins every time we turn around in our patient care we are going to be looking at "Can I do that" because there is a patent dealing with the procedure I

want to do today, whose attorney do I discuss this with, how do I provide the royalties?

There are other procedures that are patented such as the sex selection process, which is one of the early patents. There have already been cases brought against university centers that have utilized it purely for the research process. If there is any remuneration to the university, they have to pay royalties to the original investigator. When you start getting into that, then you make medicine even more complex than it already is.

Mr. GORE. Let me ask you about the advantages of the freezing procedures. First, maybe we can do it quicker if I try to state them and then you correct where I am going wrong.

No. 1, by freezing extra embryos that were created during an initial try at pregnancy, you are able, if the initial pregnancy fails, to attempt a second pregnancy without exposing the woman to the risk of the surgical extraction of another egg.

That is the first advantage, correct?

Dr. MARRS. That is correct.

Mr. GORE. The second advantage is that the woman does not have to use the drugs that are necessary to stimulate the production of eggs just prior to the egg being withdrawn.

Dr. MARRS. That is a theoretical consideration presently. We don't know yet from the clinical trials that have been performed whether that is actually going to bear out in clinical practice. Theoretically if we don't stimulate the woman to produce multiple eggs but instead allow her to undergo her normal ovulatory process with her normal hormonal fluctuations there may be a better advantage for implantation to occur.

This is similar to what Dr. Buster is doing as far as his research, looking at the rate of implantation in a nonstimulated cycle. Theoretically we believe that it may be more advantageous for that embryo to implant in nonstimulated environment or where the woman hasn't had a general anesthetic or had an operative procedure. All of those factors may be important in the implantation process.

Mr. GORE. Is there a third advantage in easier synchronicity?

Dr. MARRS. Not really because our ability to time and monitor the ovulatory process is very, very good today whether it is in a stimulated or nonstimulated environment.

Mr. GORE. So there is one real advantage. You lessen the medical risk to the mother and then there is the theoretical advantage which from a common sense standpoint, you would also seem to reduce risk, that is it gives you the ability to implant the embryo without the presence of anesthesia or the drugs used to stimulate ovulation?

Dr. MARRS. There is another theoretical consideration that we are looking at coming from the work that Dr. Buster has done looking at the rate of implantation based on the developmental stage of the embryo, for instance what is the rate of implantation with a two-cell versus a four-cell versus an eight-cell versus a blastocyst.

Mr. GORE. A blastocyst, being what, 100 cells?

Dr. MARRS. What he showed you on the screen?

Mr. GORE. Basically—

Dr. MARRS. That is the final stage of development before the embryo actually hatches out of the membrane covering it and in a short time attaches to the uterine wall. That is the end stage that we would see in a preimplantation embryo. The theoretical situation is that possibly the more advanced you get, the closer to a blastocyst, the more likely implantation may occur. So with the cryopreservation system because you are not worried about getting the embryos back into the uterine cavity during the stimulated treatment cycle, you can allow an extra 24 hours or 48 hours of growth, and therefore you have a more advanced embryo, you may increase the possibility of implantation. That is still theoretical. We don't have proof yet other than the fact these two pregnancies came about with blastocyst transfers.

Mr. GORE. One of the disadvantages, and some people wouldn't call it a disadvantage, I think I would, is that you are confronted with the dilemma of what to do with extra embryos that are not used for treating the pregnancy.

Dr. MARRS. Well, first of all, we need—yesterday one of the things that concerned me especially in the afternoon was a discussion of all these embryos that we have available to us to split, divide, freeze, hold and then decide what the children look like—all that is a very nonrealistic approach today. It may become more realistic in the next 5 to 10 years, but today it is totally unrealistic to even discuss those things because they just are not viable. We don't have embryos for everyone.

Mr. GORE. You don't have embryos for everyone. We just heard Mrs. Bassi say—

Dr. MARRS. She said that she would allow us to perform research on embryos that were not utilized. We have no established protocols for any research procedures on human embryos because we don't have embryos. We have embryos that are stored and that will be utilized ultimately in those patients. You have to get back to the concept of IVF, where do we stand with the effective rate of pregnancy with IVF procedures.

In the best clinics around the world, we are talking about around a 25-percent success rate.

Mr. GORE. So you are using them all for implantation?

Dr. MARRS. Now we are utilizing embryos, whether fresh or cryopreserved, for those patients as a pregnancy-initiating process.

Mr. GORE. But excess embryos are being used elsewhere for research and experimentation, are they not?

Dr. MARRS. If you are talking about the European theater, yes, they are, but they do not have a cryopreservation system at present. In the United States, embryos that are produced, whether there are four, five or six embryos, those embryos are being replaced into the uterine cavity during the treatment cycle if they are viable. If the program such as ours has a cryopreservation system then we would utilize those embryos that we consider extra to be stored for that patient. If you look at the possibilities that will arise, for instance, patients that have become pregnant in our program—and we have several patients that have become pregnant that have embryos that are stored—after they deliver their child, they then have the opportunity to say, "I would like a second child," and therefore we would utilize their one or two or three em-

bryos that are stored in the freezing system for an attempt at the second child.

They may also say after delivering their child, "We only wanted one child. You have two frozen embryos that are in the cryopreservation system, we have decided that we want you to utilize it for donation, and that is acceptable and they have gone through the concept procedure prior to freezing. They may also say we want you to utilize it for any approved research. At that point in time, we would then begin to develop research protocols——

Mr. GORE. But you haven't done that yet?

Dr. MARRS. Not yet.

Mr. GORE. Others have, haven't they?

Dr. MARRS. To my knowledge there have not been any research protocols being utilized in the centers in the United States.

Mr. GORE. I am not sure that is correct.

Dr. BUSTER, do you know of research being done on embryos?

Dr. BUSTER. No. I agree. I am not aware of any research being done right now on human embryos. I think that the programs are either replacing them or planning to freeze them.

Mr. GORE. I understand that there is such research.

Dr. MARRS. There is overseas.

Dr. BUSTER. Absolutely.

Dr. MARRS. There is no question about it and that is what has created a lot of discussion in this country, to my knowledge, and I have a very close association with programs in the United States.

Mr. GORE. Well, if there is no research being done on embryos in the United States right now, then that is interesting.

Dr. MARRS. It doesn't mean that we shouldn't address the issue.

Mr. GORE. I know it has been done in the United States. Perhaps it is not being done now.

Dr. BUSTER. On abortions of fetuses, I think is what you are thinking about, but not on these very, very early preimplantation embryos.

Mr. GORE. Dr. Wentz is in the back of the room. Didn't Dr. Soupart at Vanderbilt conduct such research?

Dr. WENTZ. The initial protocol that received scientific approval was entitled "Cytogenetics of the Preimplantation Embryo." This was a safety study to investigate the fertilized egg as to its genetic components. The research was never done because although it was approved scientifically, it was never funded and therefore the only work available that had been done in this country was not approved and not accomplished.

There is, however, one additional paper in the literature of which I am aware that is a project performed by Dr. Taymor in Boston using oocyte from either individuals undergoing laparoscopic sterilization or other prearranged conditions. These oocytes were not to be used for the purpose of inducing a pregnancy in that woman. That was agreed, consented, informed ahead of time.

Those oocytes were fertilized in vitro and there was an examination of them in terms of not their genetic makeup, but some of the mechanisms of the nuclei. This, to my knowledge, is the only work that has been done in the United States.

Mr. GORE. Thank you very much. I had a feeling we would get a thorough answer and I appreciate it.

The freezing, if you don't freeze, then you have to use them right away or else they are discarded. With freezing, you are postponing that decision, but it also opens the very real possibility that within a short period of time we are going to be confronting this question here in the United States, and this is one of the reasons why—

Dr. MARRS. I think it is important to discuss and I think we should make guidelines for the future. I don't think we can ignore the possibility because as we have seen in the last 2 years, our ability to produce more and more eggs with resultant increase in embryo numbers, has led us into the freezing area and that ultimately will lead us into what type of ethical research can be performed on these so-called extra employee.

Mr. GORE. What percentage are being discarded?

Dr. MARRS. To my knowledge, there are no embryos considered viable or normal being discarded at the present time. The only embryos that would not be utilized is an embryo that develops from an abnormal fertilization. There is a process called polyspermic fertilization where more than one sperm cell enters the egg and therefore you have too many chromosomes. That is an embryo that may develop, but it has usually a 69-chromosome component rather than 46 and that is something we would not knowingly transfer back to the donor.

Mr. GORE. You say in your statement that IVF will eradicate human infertility. Maybe it is a definitional problem, but you are treating the symptom rather than removing the cause of the disease.

Dr. MARRS. There is no way to remove the cause when a woman has both fallopian tubes removed surgically. We have done studies at our institution looking at tubal grafting procedures, different types of materials for replacing it and it doesn't work.

Mr. GORE. But there are other causes, are there not, that may be susceptible to cure in the future?

Dr. MARRS. I didn't mean that statement to sound like IVF was the only way to eradicate the infertile population. I think it is one mechanism that we have available today.

Mr. GORE. Fifteen percent of the people fall in this infertile category. What percent of that infertility is genetically based?

Dr. MARRS. A very small percent.

Mr. GORE. Most of it is caused by—

Dr. MARRS. Most of it is caused by mechanical processes, anatomical changes, problems primarily due to infectious diseases.

Mr. GORE. Birth control procedures?

Dr. MARRS. Yes, ectopic pregnancy, whether that comes about after contraceptive use or is endogenous with the individual. Up to 40 percent of infertility may be due to mechanical pelvic factors.

Dr. BUSTER. There is a substantial percentage where we don't know the cause and there may be an additional genetic component with that.

Mr. GORE. Has the American Fertility Society or any other professional society set up an ongoing group to study the ethical and legal questions involved with these technologies?

Dr. MARRS. As a matter of fact, while we are here, the Executive Committee of the Fertility Society is meeting. We are meeting, discussing recommendations that we have submitted. There is a

standing committee right now within the society that is charged with establishing a special interest group for in vitro fertilization.

Mr. GORE. Does it include lay persons as well as medical?

Dr. MARRS. At the present time, it includes M.D.'s and Ph.D.'s and this is an organizing body. We have submitted a whole list of recommendations for the establishment of this group. One of the recommendations and one of the considerations this week by the society is to establish some sort of review mechanism, a review board, if you will, or a board that will set up some kind of ethical and scientific guidelines for the upcoming procedures that we are going to be looking at in the future. Basically—and that would include lay people as well as scientists if that board was going to have any credibility.

Mr. GORE. I forgot to ask you, Ms. Imhof, whether or not you are paid for your donations.

Ms. IMHOF. They compensate me for my time is what it works out to, so it is \$5 for each time I give blood. That covers basically my mileage for gasoline and \$50 for the insemination because that takes a little bit longer, but I am not doing it for the pay. It is just if I have to have a baby sitter, it is nice to pay the baby sitter.

Mr. GORE. What is the total payment for a month cycle?

Ms. IMHOF. It can run anywhere from, what, \$100 to \$150, \$200, depending on—one month I was inseminated twice and so that was a little bit more and then it is \$50 for the lavage done. It depends on how many times you have to have the lavage done and how many times you are inseminated.

Mr. GORE. How many times do you have the blood checked?

Ms. IMHOF. That is normally 4 or 5 days.

Mr. GORE. There are many other questions I would like to explore with you all, but as you can see from the clock, we have spent a great deal of time with this panel already and we have another and we are going to have to move on. I want to thank all of you for coming. It has been an enlightening and helpful discussion. I have learned a lot from it and I hope it will be worthwhile in helping us better address these questions that surround the medical miracles that are being performed.

I would like to thank you for appearing today. You are welcome to stay for the panel of ethicists coming up next. I am going to call them to the table at this time.

Let me call up the second panel to the witness table at this point.

Dr. LeRoy Walters, director of the Center for Bioethics at the Kennedy Institute of Ethics at Georgetown University; Prof. Samuel Gorovitz, University of Maryland, Department of Philosophy; Dr. Donald McCarthy, director of education with the Pope John XXIII Center in St. Louis.

Let me note for the record that we have a prepared statement from Dr. Richard McCormick who is director of the Kennedy Institute of Ethics at Georgetown University. Dr. McCormick was here this morning but has recently had open heart surgery and was not feeling well as an after effect of that surgery, and we, of course, excused him under those circumstances so that he could get the rest and recuperation that he needs and, without objection, his pre-

pared statement will be made a part of the record at this point in the record.

[The prepared statement of Dr. McCormick follows:]

*SHORT**lay in*Procreative Technologies

Testimony Before
The Subcommittee on Investigations and Oversight
August 9, 1984

Richard A. McCormick, S.J.
Rose F. Kennedy Professor of Christian Ethics
Kennedy Institute of Ethics
Georgetown University

In addressing the ethical issues surrounding in vitro fertilization, I speak as a Roman Catholic theologian, as one from a tradition but not one commissioned to speak for it. My analyses and judgments, therefore, are my own. My testimony will touch on four points: (1) the relation of ethics and public policy; (2) the criterion for judging the moral character of human actions; (3) the values at stake in procreative technologies; (4) a basic ethico-prudential judgment.

1. Morality and public policy. This is a large question with many dimensions and I cannot discuss them all here. I want to make a single point: morality and public policy are both related and distinct. They are related because morality, at one level, is concerned with the rightness and wrongness of human conduct. Public policy has an inherently moral character due to its rootage in existential human goals or ends. Briefly, the welfare of the community--the proper concern of law--cannot be unrelated to what is judged promotive or destructive to human persons, to what is judged morally right or wrong.

The two notions are, however, distinct. Public policy is concerned with the welfare of the community. Only when individual acts have ascertainable consequences on the maintenance and stability of society (welfare of the community) are they the proper concern of public policy.

I say this because many Americans, being a notoriously litigious people, often simply collapse policy into their own moral convictions. Symbolic of this is the oft-heard shout "there 'oughta' be a law."

What immoral actions affect the welfare of the community in a way that demands legislation? All actions that have ascertainable public consequences on the maintenance and stability of society are matters of legitimate concern to society. But it is feasibility that tells me whether they should be in the penal code or not, whether they should be publicly controlled. Let me cite the renowned John Courtney Murray, S.J., to elaborate the concept.

"A moral condemnation regards only the evil itself, in itself. A legal ban on an evil must consider what St. Thomas calls its own 'possibility.' That is, will the ban be obeyed, at least by the generality? Is it enforceable against the disobedient? Is it prudent to undertake the enforcement of this or that ban, in view of the possibility of harmful effects in other areas of social life? Is the instrumentality of coercive law a good means for the eradication of this or that social vice? And, since a means is not a good means if it fails to work in most cases, what are the lessons of experience in the matter?" (We Hold These Truths, 166-7)

In summary, where public policy on procreative technologies is in question, we do not ignore morality, not at all. But after determining it, we must move it through the prism of feasibility and ask questions such as: Will the proposed law achieve what we want and no more? Will it have the general support of the public? What are its likely consequences in other areas of public concern?

2. The criterion for judging the moral character of human actions.

Over the centuries people have used a variety of criteria to judge the ethical character of human actions. However, I believe that many philosophers and theologians would agree with the criterion suggested

by the Second Vatican Council: the person integrally and adequately considered. This refers to the human person in all of his/her essential aspects. The following aspects may be mentioned: (1) a subject, normally called to consciousness, to act according to conscience, in freedom and in a responsible way; (2) An embodied subject; (3) an embodied subject that is part of the material world; (4) persons are essentially directed toward one another; (5) persons need to live in social groups with structures and institutions worthy of persons; (6) the human person is called to know and worship God; (7) the human person is a historical being with continuing new possibilities; (8) all persons are utterly original and fundamentally equal.

According to this criterion an action is morally right if it is beneficial to the human person adequately considered in him/herself (n.1,2) and in relationships (3,4,5,6). In weighing the morality of procreative technologies it is our task to discern this promotive or destructive character of the intervention. I mention these many dimensions of human personhood as the criterion of judgment to emphasize the fact that ethical analysis cannot be reduced to the overriding importance of a desire for a child, or for one's genetic child, or for a certain kind of child. Too often such reductionism characterizes public exchange on these matters.

To determine whether a particular action is beneficial or detrimental is not always an easy task because our actions are often characterized by ambiguity. That is, they are simultaneously both detrimental and beneficial, containing values and disvalues. An amputation may save one's life (value) but necessarily involves a

burden (disvalue) for the person. To bring focus to such ambiguity often requires experience and time.

3. The values at stake in procreative technologies. By "values at stake" I refer to dimensions of human flourishing that can be affected by procreative technologies and the cultural judgments and directions they embody and foster. These dimensions are specifications of our embodiment and our essentially relational character. I would list the following: the meaning of the family; ^{the meaning of self-identity;} the meaning of sexuality and marriage; the sanctity of individual human life. Our task, then, is to discover whether and how new procreative technologies may affect these dimensions of human flourishing. Will they, at some point, tend to weaken the family as a basic social unit by affecting its biological rootage? Will they tend to dissolve or weaken the sense of individual self-identity by obscuring or dispersing its source? Will they support and strengthen the integrity of our sexuality, or tend to displace or mechanize it? Will experimentation on embryonic life tend to dissipate our respect for persons? Indeed, is it in itself an act of disrespect? People are likely to reveal different assumptions in answering these questions. For this reason they are likely to arrive at different conclusions. This makes public policy more difficult because the feasibility test is strained by public pluralism.

4. A basic ethico-prudential judgment. I use this cumbersome term ("ethico-prudential") to indicate that I am not proposing here a norm that can be established by firm and broad empirical data or tested experience, or absolutely convincing moral analysis. Rather, I am proposing a safeside moral rule of prudence against the slide to abuse. (Thus the

term "ethico-prudential") This rule is: procreation of children should be restricted to marriage. Why? Because I believe there are risks (I did not say certainties) in extending approval beyond this, and these risks are to the basic dimensions of our flourishing. Such risks to basic values outweigh, in a prudential calculus, individual procreative desires or needs. We might summarize: individual benefit versus institutional risk of harm. The latter ought to take precedence.

According to this ethico-prudential rule, the following would not achieve ethical approval:

- artificial insemination by donor
- in vitro fertilization involving sperm or ovum from a donor
- surrogate wombs
- embryo freezing with the possibility of surrogate womb
- a fortiori, the commercializing of any of these procedures.

This ethico-prudential rule corresponds to that developed by the Ethics Advisory Board (of the former DHEW). Events since that time have done nothing, in my judgment, to undermine the wisdom of that stance by the E.A.B.

A final word on experimentation on the embryo. From an ethical point of view, I believe a similar ethico-prudential rule of rejection is justified. I do not base this on the certain personhood of the embryo or its achieved individuality (as some would), but on the respect due to germinating human life or its potentiality. If such respect means anything, it means a strong presumption against experimentation. This

exclusionary rule is rooted in the respect we owe to that which is enroute to becoming personal life, not on the certain violation of personal life. Furthermore, such a rule is recommended by the risk of erosion of respect for human life that might occur without it.

What I have been proposing are moral (ethical) positions. To what extent and how these positions can be related to public policy in our pluralistic society is your unenviable task to determine if indeed there is agreement with my moral analyses. I am certain that some interventions I have excluded at the level of moral judgment would fail the test of feasibility should there be attempts to exclude them by law. For instance, there is probably neither the will to enforce nor the possibility of enforcing a policy ban on donor insemination, and indeed, other variations of procreative interventions. The same is not true of experimentation on embryos.

Mr. GORE. Likewise, without objection, the statements of our three witnesses who are here will be made a part of the record in full. I want to invite you to summarize your statements if you care to do so.

I want to welcome all of you and Dr. LeRoy Walters, you have helped us in the past. We are indebted to you for your prior assistance and we look forward to your statement at this point.

Please proceed.

STATEMENT OF LeROY WALTERS, DIRECTOR, CENTER FOR BIOETHICS, KENNEDY INSTITUTE OF ETHICS, GEORGETOWN UNIVERSITY

Dr. WALTERS. Mr. Chairman, ladies and gentlemen, my remarks will be divided into two parts. First I will discuss several emergent issues connected with clinical in vitro fertilization or embryo transfer. Second, I will turn to the question of research involving early human employees.

In vitro fertilization and embryo transfer are normally provided to alleviate the infertility of a married couple. In the typical case, gametes are provided by the members of the couple, and no freezing and thawing of the embryos are required. There is broad, but by no means universal, acceptance of this kind of clinical fertilization and embryo transfer in marriage. I think that cuts across both the general public and within the ethics community. There are, however, two developments on the horizon that seem to raise ethical and perhaps legal questions as well. They are freezing and do-

nation. In addition, we as a nation face the more general problem that we have seen illustrated in the earlier panel—trying to develop a coherent and humane public policy on infertility treatment.

The first development requiring special attention is the freezing and storage of sperm, eggs or embryos. Since the freezing and storage technique especially as applied to eggs and embryos reduces the number of surgical procedures that a woman must undergo, there is a *prima facie* ethical case in favor of the freezing technique currently with embryos and perhaps some day with human eggs as well, but there are problems that cryopreservation raises even when donation is not involved.

The first is what we might call, for lack of a better term, the problem of ownership. The second is the problem of unanticipated contingencies like marital separation or the death of one or both spouses. The Warnock Committee in Great Britain has, I think, provided us useful guidance on both of these questions.

On the question of ownership, the Warnock Committee recommended that there be no ownership of human embryos, but rather that the genetic parents have the responsibility to determine what shall be done with the embryos within constraints that are, of course, set by the society at large. The Warnock Committee also recommended that to cope with unanticipated contingencies, there should be an automatic 5-year review of each deposit of semen or eggs and that there be an upper limit on the length of time that human embryos may be stored by freezing. To these recommendations I would add that parental decisions about what should be done with stored gametes or stored embryos should be made and documented before the freezing is undertaken.

The second kind of ethical question that arises is the donation or possible commercial transfer—sale, if you will—of human gametes or embryos. Here again there are serious practical problems. The first is appropriate screening for donors. I might say that in this case, the newer technologies seem to be doing a much better job than the older technology of artificial insemination by a donor. What we have heard about the newer programs with *in vitro* fertilization suggests that they are being much more thorough in screening than sperm banks are being at the present time.

A 1977 survey of physicians providing artificial insemination in the United States revealed a serious lack of donor screening and general recordkeeping. According to the researchers, who published their data in the *New England Journal of Medicine* in 1979. "The donors in our sample were subjected to very little genetic screening. Family histories were usually superficial and biochemical tests were rarely performed." Fewer than a third of the physicians kept any permanent records on semen donors. That means if one ever had to go back and try to trace whether a semen donor had a genetic problem, it could not be done in two-thirds of the cases. We clearly need uniform national standards on the question of recordkeeping and screening of donors of semen, eggs, or embryos.

A second and more controversial question is whether human gametes or embryos should be donated and received as gifts or whether they should be bought and sold. This question has obvious parallels to the question of buying and selling human organs or tissues,

a question that your subcommittee devoted detailed attention to last November.

From an ethical standpoint, the establishment of commercial embryo banks would seem at best morally dubious. There are none now, but one can see that the technical possibility will be here very shortly. While human embryos are clearly not human infants, the practice of buying and selling human embryos seems more closely analogous to baby selling than to the sale of sperm or eggs. My recommendation is that human embryos should be placed in a category of respect similar to that reserved for human organs or human cadavers and that their sale or purchase should be legally prohibited.

Ethical arguments about the sale or purchase of sperm and eggs are even less easy to resolve. However, both the British and the French are as a matter of public policy moving toward voluntary nonprofit systems for recruiting semen donors. The major practical advantage for these nonprofit systems is that they reduce the likelihood that sperm or egg donors are suppressing information about medical disabilities or familial genetic disorders so what I recommend is that we consciously try to move toward the kind of system that we have for whole blood donation in the United States where 97 percent of the whole blood is collected in the nonprofit voluntary sector.

The third ethical issue connected with donation has arisen only in connection with embryo donation following uterine lavage. It is the issue of patenting medical procedures that may help to alleviate infertility. According to several published reports and testimony that we heard earlier this morning, commercial sponsors of the uterine Lavage technique seek to patent not only the catheter and solution employed, but also the procedure for flushing the uterine content several days after artificial insemination.

I have no criticism of the patent system in general. It seems to me to provide an orderly way for the development and diffusion of new knowledge and techniques. My question is about a specific application of the patent system; namely, in the reproductive context. The proposed patent would require that all physicians wishing to employ a certain medical procedure that is potentially useful to their patients must purchase a license before being authorized to perform the procedure. If that system had been in effect when cardiac catheterization or kidney transplantation were first developed, it seems likely that the diffusion of these new technologies would have been delayed and that the cost to the patient would have been increased. Since the patent system is controlled by Federal law and since this subcommittee has taken the lead in looking at ethical issues in the biomedical field, the subcommittee may at some future point want to devote detailed attention to the generic problem of process patents in medicine.

I turn now from a discussion of specific questions concerning in vitro fertilization or embryo transfer to interesting and difficult issue of formulating a coherent national policy on infertility treatment. The exact extent of involuntary infertility in the United States is not known. However, the best available estimates reveal a problem of major proportions. According to a study published in 1982 by the National Center for Health Statistics, more than 2 mil-

lion married women in the United States who want to conceive and bear a child are prevented by involuntary infertility problems from doing so.

What this means is that one of every 14 married couples in the United States is afflicted by involuntary infertility.

Now, the extent to which these couples are able to secure help in overcoming the problem of involuntary infertility depends very heavily on their level of income and on the quality of private or public health insurance that they have. Private health insurers have been notably very cautious about reimbursing for in vitro fertilization or embryo transfer while state programs have made infertility treatment a low or nonexistent priority.

U.S. couples receiving in vitro fertilization typically expect to incur costs of approximately \$3,000 to \$5,000 per month for a 15- to 30-percent chance of initiating a pregnancy. The setting of priorities among medical problems and medical treatments is notably a complex process and there is no simple formula for determining what relative priority heart transplants, kidney transplants, and infertility treatment should have. However, the process of setting those priorities should in my view be opened up.

Specifically, the kind of standards that are set by the Federal Government for State medical assistance programs or federally reimbursed health maintenance organization programs should be re-examined and there should be an attempt to look more explicitly at this problem of involuntary infertility and I think consumer input into the process of setting priorities in this area should also be invited. Perhaps the appropriate officials at the Health Care Financing Administration could make suggestions of how this process could be opened up.

I turn now to the disputed question of research involving early human embryos. The most fundamental question in the embryo research debate is the following: What are our moral obligations to those primitive beings that we who can reason have learned to call human embryos? I think the answer to this question will inevitably be a judgment, a conclusion based on both factual and normative premises. Those who argue that our moral obligations to early human embryos are as strong as our obligations to newborn infants reach this conclusion on the basis of the embryonic genotype and the embryo's potential to become a human person.

Conversely, those who join Aristotle in accepting a developmental view of prenatal life conclude that our moral obligations to human embryos are relatively weak, growing stronger as the embryo becomes a fetus and very strong when the fetus becomes viable. On this view our *prima facie* obligation to respect and protect early human embryos may in some cases be outweighed by our duty to perform research intended to reduce the suffering of present and future patients. Both of these ethical positions are strongly recommended in the Warnock Committee report and they led to the major disagreement embodied in the final report of the Warnock Committee.

A fair and prudent public policy will in my view give due consideration to both of these seemingly irreconcilable perspectives on the ethics of research with early human embryos. This policy would on the one hand require would-be researchers to demon-

strate that their proposed work with human embryos seeks important knowledge that cannot be gained in any other way. On the other hand, this policy will permit research with early human embryos to proceed when researchers are able to provide the required justification.

My specific proposal for effective oversight of research with early human embryos is a procedural one. A national review committee on research involving early human embryos should be established to evaluate each program to perform embryo research in the United States. The committee should be comprised of experts in laboratory science, medicine, ethics and law. Its meetings should be open to the public and it should submit an annual report to the Congress, the President and the Secretary of Health, Education and Welfare—I am sorry, of Health and Human Services. That report should indicate the number of proposals received during the previous year as well as the justifications provided for the approved research projects.

In evaluating specific research protocols, the proposed national review committee would undoubtedly need to confront several general questions about the research, among them the kinds of questions that were discussed in the Warnock Committee report.

For example, for what period of time should embryo culture be permitted? Seven days, as in Australia? Fourteen days, as recommended in Great Britain? Or 21 days, as is the current practice in Denmark?

Second, should research be restricted to embryos that are left over from the clinical context or should the deliberate creation of embryos for research purposes be permitted?

And third, should only research that has obvious and immediate clinical application be permitted or should basic research that seeks fundamental knowledge through work involving early embryos also be approvable?

Fortunately, this proposed national review committee will have a great deal of reading material to look through as it confronts these issues. It will have an ethics advisory board report from 1979 from this country, a report of over a thousand pages. It will have the Warnock Committee report from Great Britain and the forthcoming Waller Committee report from Australia.

In conclusion, the clinical uses of in vitro fertilization and embryo transfer have advanced rapidly in this country with little governmental involvement of any kind. I have tried to argue that that is appropriate and that, if the Congress can nudge the professional societies to take additional steps on such issues as the screening of donors that the professional societies can perhaps assume primary responsibility in the clinical context. Here I would see the major role of the Congress being to encourage the development of a more coherent national policy for infertility treatment in general and especially for the coverage of infertility treatment.

But in the research context, we have stood still since May 4, 1979. At that time, a comprehensive report went forward from an ethics advisory board to the Secretary of an agency that at that time was called the Department of Health, Education and Welfare. Nothing has been done since that time, and here I think the gov-

ernment owes its citizens a clear decision, and if the decision is affirmative, then it owes its citizens an appropriate oversight body.

Thank you.

[The prepared statement of Dr. Walters follows:]

HEARINGS ON HUMAN EMBRYO TRANSFER
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
AUGUST 8-9, 1984

STATEMENT ON ETHICS AND IN VITRO FERTILIZATION

LeRoy Walters, Ph.D.
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Kennedy Institute of Ethics
Georgetown University
Washington, D.C. 20057

Mr. Chairman, my name is LeRoy Walters. I am professionally trained in ethics and currently serve as Director of the Center for Bioethics at the Kennedy Institute of Ethics, Georgetown University. Since 1978 when I assisted the Ethics Advisory Board of the United States Department of Health, Education, and Welfare in compiling a report on human in vitro fertilization, I have had an active interest in the topic of this hearing.

The remarks that follow are divided into two parts. First, I will discuss several emergent issues in the clinical use of in vitro fertilization (IVF) or embryo transfer (ET). Second, I will consider the question of research involving early human embryos.

I. Clinical In Vitro Fertilization or Embryo Transfer

IVF and ET are normally employed to alleviate the infertility of a married couple. In the typical case gametes are provided by the members of the couple, and no freezing and thawing of the embryos are required. There is broad, but by no means universal, acceptance of IVF in these circumstances -- both by the general public and within the ethics community.

There are, however, two developments on the clinical horizon that require ethical and perhaps also legal attention -- freezing and donation. In addition, we as a nation face the more general problem of developing a

coherent and humane public policy on infertility treatment.

The first development requiring ethical attention is the freezing and storage of human sperm, eggs, or embryos. The freezing of human semen has been practiced for several decades, while the freezing of human embryos is a relatively recent phenomenon. At present, the freezing and thawing of human eggs renders impossible their fertilization and subsequent embryonic growth. However, improvements in cryopreservation techniques may one day make the freezing and thawing of human eggs feasible.

Since the freezing and storage of human embryos or eggs would help reduce the number of surgical procedures undergone by a woman who desires to become pregnant, there is at least a prima facie ethical argument in favor of using this technique. There are, however, attendant practical problems connected with cryopreservation, even in the non-donation context. The first is the problem that might be called, for lack of a better word, the question of "ownership." The second is the problem of unanticipated contingencies like marital separation, divorce, or the incapacity or death of one or both spouses.

The Warnock Committee in the United Kingdom has provided helpful guidance on both of these issues (1). It recommends that there should be no right of ownership in a human embryo but that the genetic parents of the embryo should have the responsibility to determine what shall be done with the embryo -- subject, of course, to any

limitations that the society may impose. The Warnock Committee also suggests that, to cope with unanticipated contingencies, there should be automatic five-year reviews of semen and egg deposits, as well as an upper time limit for the storage of embryos. To these recommendations I would add that parental decisions about the future of frozen gametes or embryos should be made and clearly documented before cryopreservation is undertaken.

From a public-policy standpoint, the freezing and storage issue may not require federal or state legislation. The American Fertility Society has already issued a statement that provides initial guidance on these issues (2). More detailed guidelines from the Society and other professional organizations may be sufficient to resolve the major remaining problems in the cryopreservation arena.

The second development requiring ethical attention is the donation or possible commercial transfer of human gametes or embryos. The donation or sale of human semen is an established practice in the United States, especially in connection with artificial insemination by donor (AID). The donation of human eggs and embryos are relatively recent phenomena, and only a few cases have been reported (3). Embryo donation can be accomplished either by means of IVF with donated gametes or through the artificial insemination of a donor woman who then undergoes uterine lavage several days after the insemination. The latter technique has been pioneered by John Buster and his colleagues at UCLA (4).

The first ethical question to be considered in the donation context is whether the attempt to move outside the family unit is morally justifiable in principle. It must be conceded that major practical difficulties surround the donation of human gametes or embryos. On the other hand, for the wife who cannot produce fertilizable eggs or the husband who cannot produce the necessary quantity or quality of sperm, there is no recourse but to go outside the family unit, in one way or another, if the couple desires to have children. Adoption is one obvious way to go outside the family, but, as is well known, healthy, adoptable infants are frequently unavailable. In addition, if only one member of a couple is infertile, techniques of assisted reproduction can allow the other member of the couple to contribute genetically to the child -- thus permitting the couple to approximate, as nearly as possible, the conventional pattern of reproduction by fertile couples. I conclude, therefore, that in cases of necessity the use by infertile couple of AID, egg donation, or even embryo donation, seems morally justifiable.

However, there are practical problems connected with the donation or commercial transfer of human gametes or embryos. I will briefly mention three such problems, beginning with the least controversial. The first problem is appropriate screening for donors. A 1977 survey of physicians providing artificial insemination in the United States revealed a serious lack of donor screening and

general recordkeeping (5). According to the researchers who conducted the national survey,

...The donors in our sample were subjected to very little genetic screening. Family histories were usually superficial, and biochemical tests were rarely performed (6).

Only 30.4% of physicians kept permanent records on donors. In the matter of donor screening and recordkeeping there is a clear need for uniform national standards. If such standards were developed and implemented by the appropriate professional societies, federal or state legislation might not be required.

A second and more controversial question is whether human gametes or embryos should be donated and received as gifts or whether they should be bought and sold. This issue has obvious parallels with the question whether human organs should be bought and sold -- a question considered in depth by this Subcommittee in its hearings of last November.

From an ethical standpoint, the establishment of commercial embryo banks seems, at best, morally dubious. While human embryos are clearly not human infants, the practice of buying and selling human embryos seems more closely analogous to baby-selling than to the sale of gametes. My recommendation is that human embryos should be placed in a category of respect similar to that reserved for human cadavers and human organs and that their sale or purchase should be legally prohibited.

Ethical arguments about the sale and purchase of human

gametes seem less easy to resolve. However, both the British and French are, as a matter of national policy, moving toward voluntary, non-profit systems for recruiting semen donors (7). The major practical advantage of such non-commercial systems is that they reduce the likelihood that sperm or egg donors will suppress information about medical disabilities or familial genetic disorders (8). Again in this case concerted action by professional bodies may facilitate the growth of a voluntary, non-profit gamete donation system and thus render legislation unnecessary.

A third issue has arisen in the reproductive context only in connection with embryo donation following uterine lavage. It is the issue of patenting medical procedures that may help to alleviate infertility. According to several published reports, the commercial sponsors of the uterine lavage technique seek to patent not only the catheter and solution employed but also the procedure for flushing the uterine contents several days after artificial insemination, in an effort to recover the early embryo (9).

The patent system in general seems to contribute significantly to the development and diffusion of new knowledge and techniques. My question concerns a specific proposed use of the patent system, namely, to require that all physicians wishing to employ a medical procedure that is potentially useful to their patients must purchase a license before being authorized to perform the procedure. Had kidney transplantation or cardiac catheterization been

patented as procedures, it seems likely that their diffusion into the clinical context would have been delayed and patient costs increased. Since the patent system is controlled by federal law, and since this Subcommittee has taken the lead in examining ethical issues in the biomedical fields, the Subcommittee may at some future time wish to devote attention to the generic problem of process patents in medicine.

I turn now from a discussion of specific questions concerning IVF or ET to the interesting and difficult issue of formulating a coherent public policy on infertility treatment. One of the major contributions of the Warnock Committee report is its clear expression of concern for the plight of couples who are involuntarily infertile. In the words of the Committee,

Parents...feel their identity in society enhanced and confirmed by their role in the family unit. For those who long for children, the realisation that they are unable to found a family can be shattering. It can disrupt their picture of the whole of their future lives (10).

As for the argument that infertility is not a disease or a true medical need, the Warnock Committee responds with a trenchant comment: "Medicine is no longer exclusively concerned with the preservation of life, but with remedying the malfunctions of the human body" (11).

The exact extent of involuntary infertility in the United States is not known. However, the available estimates reveal a problem of major proportions. According

to a recent study published by the National Center for Health Statistics, there are 4.3 million currently married women in the United States aged 15 to 44 years who experience impaired fecundity. Of these, 47.3%, or more than 2 million women, want to conceive and bear a child but are prevented by infertility problems from doing so (12). Thus, the best data available suggest that 1 of every 14 married couples in the United States is afflicted by involuntary infertility.

The extent to which infertile couples are able to secure medical help for their problem is heavily dependent on their level of income and the breadth of coverage provided by their private or public health insurance plans. Private health insurers have been notably cautious about reimbursing the costs of IVF, while state and federal medical assistance programs have made infertility treatment a low or nonexistent priority. U.S. couples receiving IVF typically expect to incur costs of \$3,000 to \$4,000 per cycle -- for a 15-20% chance of achieving a pregnancy.

The setting of priorities among medical treatments is a notably-complex problem, and there is no simple formula for determining what relative priority should be accorded to the treatment of infertility. However, the process of determining what constitutes an acceptable set of coverages for state Medicaid plans and for federally-reimbursed health maintenance organizations should, in my view, be modified. Specifically, it should devote more explicit attention to

the infertility problem of the nation and to consumer views on the relative importance of that problem. The appropriate officials at the Health Care Financing Administration could perhaps suggest ways to include these concerns in the policymaking process.

II. Research Involving Early Human Embryos

Research with human embryos and research with human fetuses are perhaps the two most controversial topics in human research in the United States today. The remarks that follow represent an attempt to identify some of the major ethical decisions that we as a society will need to make regarding research with human embryos.

The most fundamental question in the embryo research debate is the following: What are our moral obligations to those primitive beings that we who can reason have learned to call "human embryos"? The answer to this question will inevitably be a judgment, a conclusion based on both factual and normative premises. Those who argue that our moral obligations to early human embryos are as strong as our obligations to newborn infants reach this conclusion on the basis of the embryonic genotype and the embryo's potential to become a human person. Conversely, those who join Aristotle in accepting a developmental view of prenatal life conclude that our moral obligations to early human embryos are relatively weak, growing stronger as the embryo becomes

a fetus and very strong when the fetus attains viability. On this view, our prima facie obligation to respect and protect early human embryos may, in some cases, be outweighed by our duty to perform research intended to reduce the suffering of present and future patients. Both of these ethical positions are strongly represented in the Warnock Committee report and led, in fact, to the major disagreement embodied in that report (13).

A fair and prudent public policy will, in my view, give due consideration to both of these seemingly irreconcilable perspectives on the ethics of research with early human embryos. It will, on the one hand, require would-be researchers to demonstrate that their proposed work with human embryos seeks important knowledge that cannot be gained in any other way. On the other hand, it will permit research with human embryos to proceed when researchers are able to provide the required justification.

My specific proposal for effective oversight of research with early human embryos is a procedural one. A National Review Committee on Research Involving Human Embryos should be established to evaluate each proposal to perform embryo research in the United States. The Committee should be comprised of experts in laboratory research, clinical medicine, ethics, and law. Its meetings should be public, and it should provide an annual report to the Congress, the President, and the Secretary of Health and Human Services concerning the number of proposals reviewed

and the justifications provided for approved research projects.

The proposed Committee resembles two other bodies. A Working Group on Human Gene Therapy is currently being established by the NIH Recombinant DNA Advisory Committee to provide national review of all proposals involving this new technique. Similarly, a current regulation of the Department of Health and Human Services (DHHS) requires review by an Ethical Advisory Board of all IVF proposals funded by the Department or any component thereof (14). This rule is inoperative because no Ethical Advisory Board exists. In addition, the Ethical Advisory Board, as envisioned in the regulations, might lack authority to review proposed research not funded by DHHS.

In evaluating specific research protocols, the proposed National Review Committee on Research Involving Human Embryos would undoubtedly need to confront several general questions about the research, among them the following:

For what period of time should embryo culture be permitted?

Should research be restricted to embryos that are left over from the clinical context, or should the deliberate creation of embryos for research purposes be permitted?

Should only research that has obvious and immediate clinical application be permitted, or should basic research that seeks fundamental knowledge through work involving early embryos also be approvable?

The National Review Committee will have ample reading material for its deliberations on these important topics,

including the 1979 Ethics Advisory Board report (15), the Warnock Committee report, and the Waller Committee report from Australia.

In conclusion, the clinical uses of IVF and ET have advanced rapidly with little governmental involvement. I have argued that the professional societies should continue to assume the primary responsibility for oversight in this arena. The Congress can assist the professional societies where necessary but should in my view concentrate its attention primarily on encouraging the development of a more coherent national policy on coverage for infertility treatment. In the research context, however, the United States is exactly where it was on May 4, 1979, when the Ethics Advisory Board delivered a comprehensive report to the Secretary of what was then called the Department of Health, Education, and Welfare. Here the government owes its citizens a clear decision and, if the decision is affirmative, an appropriate oversight body.

NOTES

1. Great Britain, Department of Health and Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology (Dame Mary Warnock, Chairman) (London: Her Majesty's Stationery Office, July 1984).
2. American Fertility Society, "Ethical Statement on In Vitro Fertilization," Fertility and Sterility 41: 12; 1984.
3. Alan Trounson, et al., "Pregnancy Established in an Infertile Patient after Transfer of a Donated Embryo Fertilised in Vitro," British Medical Journal 286: 835-838; 1983. John E. Buster, et al., "Non-Surgical Transfer of In Vivo Fertilized Donated Ova to Five Infertile Women: Report of Two Pregnancies," Lancet 2: 223-224; 1983.
4. Mario Bustillo, et al., "Nonsurgical Ovum Transfer as a Treatment in Infertile Women: Preliminary Experience," JAMA 251: 1171-1173; 1984.
5. Martin Curie-Cohen, et al., "Current Practice of Artificial Insemination by Donor in the United States," New England Journal of Medicine 300: 585-590, 1979.
6. Curie-Cohen, p. 586.
7. Great Britain, Report of the Committee of Inquiry, p. 27.
8. Curie-Cohen, p. 588.
9. See, for example, Harris Brotman, "Human Embryo Transplants," New York Times Magazine, January 8, 1984, pp. 42ff., and George J. Annas, "Surrogate Embryo Transfer: the Perils of Patenting," Hastings Center Report 14: 25-26; June 1984.
10. Great Britain, Report of the Committee of Inquiry, p. 8.
11. *Ibid.*, p. 9.
12. William D. Mosher and William F. Pratt, "Reproductive Impairments among Married Couples: United States," Vital and Health Statistics, series 23, Data from the National Survey of Family Growth, no. 11, National Center for Health Statistics, December 1982, pp. 13, 32.
13. See especially pp. 90-94 of the report.
14. Code of Federal Regulations 45, paragraph 46.204(d).
15. United States, Department of Health, Education, and Welfare, Ethics Advisory Board, HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer (2 vols.; Washington, D.C.: DHEW, May 4, 1979).



JOSEPH AND ROSE KENNEDY INSTITUTE OF ETHICS
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WASHINGTON, D.C. 20057

202-625-2386

September 14, 1984

The Honorable Albert Gore, Jr.
Chairman, Subcommittee on Investigations
and Oversight
Committee on Science and Technology
U.S. House of Representatives
1131 Longworth Building
U.S. Capitol
Washington, D.C. 20515

Dear Mr. Gore:

This brief letter follows up on my testimony of August 9, 1984, concerning ethics and in vitro fertilization.

In my testimony I expressed concern about the potential implications for the provision of health care of patenting medical procedures. As the enclosed excerpt from the British Patents Act 1977 indicates, the United Kingdom has decided to exclude from patentability any "invention of a method of treatment of the human or animal body or of diagnosis practiced on the human or animal body" (Section 4.2, p. 558).

Further research on the background of this provision and its effect in British practice might be illuminating to us in the United States as we seek to develop our own national policy.

Sincerely yours,

A handwritten signature in cursive script that reads "LeRoy Walters".

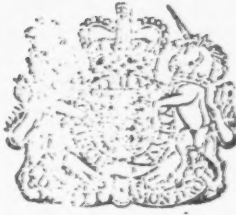
LeRoy Walters, Ph.D.
Director
Center for Bioethics

LW:mab

Enclosures

cc: Mr. Robert B. Nicholas
Mr. James E. Jensen

British Patent Law 1977
(not entire text)



THE
PUBLIC GENERAL ACTS
AND GENERAL SYNOD MEASURES
1977

[IN THREE PARTS]

PART I
(Chapters 1-38)

with
*Lists of the Public General Acts,
Local Acts and General Synod Measures
and an Index*

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Patents Act 1977

1977 CHAPTER 37

An Act to establish a new law of patents applicable to future patents and applications for patents; to amend the law of patents applicable to existing patents and applications for patents; to give effect to certain international conventions on patents; and for connected purposes. [29th July 1977]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

PART I

NEW DOMESTIC LAW

Patentability

1.—(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say—

- (a) the invention is new;
- (b) it involves an inventive step;
- (c) it is capable of industrial application;
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;

and references in this Act to a patentable invention shall be construed accordingly.

PART I

(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of—

- (a) a discovery, scientific theory or mathematical method;
- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted—

- (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour;
- (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

(4) For the purposes of subsection (3) above behaviour shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in the United Kingdom or any part of it.

(5) The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

Novelty.

2.—(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of

that invention, if the following conditions are satisfied, that is to say—

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- (a) that matter was contained in the application for that other patent both as filed and as published; and
- (b) the priority date of that matter is earlier than that of the invention.

(4) For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either—

- (a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person—
 - (i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or
 - (ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it;
- (b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor; or
- (c) the disclosure was due to, or made in consequence of, the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.

(5) In this section references to the inventor include references to any proprietor of the invention for the time being.

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(6) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance

PART I or composition in any such method does not form part of the state of the art.

Inventive step. 3. An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

Industrial application. 4.—(1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

(3) Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.

Priority date. 5.—(1) For the purposes of this Act the priority date of an invention to which an application for a patent relates and also of any matter (whether or not the same as the invention) contained in any such application is, except as provided by the following provisions of this Act, the date of filing the application.

(2) If in or in connection with an application for a patent (the application in suit) a declaration is made, whether by the applicant or any predecessor in title of his, complying with the relevant requirements of rules and specifying one or more earlier relevant applications for the purposes of this section made by the applicant or a predecessor in title of his and each having a date of filing during the period of twelve months immediately preceding the date of filing the application in suit, then—

(a) if an invention to which the application in suit relates is supported by matter disclosed in the earlier relevant application or applications, the priority date of that invention shall instead of being the date of filing the application in suit be the date of filing the relevant application in which that matter was disclosed or, if it was disclosed in more than one relevant application, the earliest of them;

(b) the priority date of any matter contained in the application in suit which was also disclosed in the earlier relevant application or applications shall be the date of filing the relevant application in which that matter

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some weakness, assumed the impregnability of a Sherman tank.

So there I was, with three dogs on the ends of strings, each with its own determined and different view concerning the most desirable direction in which to proceed, and the prospect of a two-mile trek along tarmac before I could rest and consider the next move.

Fortunately, a fellow dog-walker turned up, even before I had finished dithering, and nobly offered me a lift. And it was a noble offer, because he owned a brand-new A-registered hatchback, all spit and polish and unsullied light grey upholstery. So into the boot went the dogs, and I with them, to keep the darlings from leaping over onto the virgin cloth.

Halfway home I let out another great wail of despair. I had suddenly realised that the house would by then have been deserted and shut, and that my door key was with the others in the Sherman tank.

Anyway, better be stranded in my own back yard than on an alien shore. At least I could let go of the dogs. But what now? No prospect of contacting my dear wife for ages, work to be done, and the cleaning lady due in half-an-hour. It was but the work of minutes to satisfy myself that all the downstairs doors and windows were firmly secured, and that even the dog flap used by the Labrador was too small to admit more than my head and one arm and shoulder. Then I saw an upstairs window slightly ajar. Out came the stepladder from the stable. I could just reach the window and push it wide, hook my hands over the sill, and haul myself up and so: the dogs stood watching from below, shouting excited approval at my feat.

When the cleaning lady arrived she was most sympathetic, and said her husband had a week off, and would I like her to give him a ring and ask him to give me a lift back to the tank to see what we could do? Splendid! So she tried but was answered by someone called Hazel she'd never heard of. It turned out she couldn't quite remember

her own number, having never rung it before, but we soon got that one sorted out, and while her husband was on his way, I assembled my car-breaking in kit—a chisel, a couple of hefty screwdrivers, and a pair of pliers, and some wire.

Ten minutes later we were at the scene of the *fores et origo* of the whole affair. While I levered the top of the locked car door a few millimetres out from the frame, he threaded in the looped wire, manoeuvred its tip with the sensitive skill of a cardiologist, plying a cardiac catheter, and ten minutes later again he had lassoed the door-lock knob, and we had won.

Now, the cleaning lady's husband is a fine fellow, but what you might call a bit of a rough diamond. Moreover he drives an old banger. And I myself, when dressed for the fens, in jeans, and a holy sweater, and bover boots, don't look exactly like the Private Secretary to Her Most Gracious Majesty the Queen. Yet while we two characters of dubious appearance, decanted from an equally dubious-looking vehicle, were busily breaking and entering the Sherman tank, two respectable citizens walked by. The first took not a blind bit of notice. The second shouted a cheery "Locked yourself out, have you?" and passed on.

Back home once again I recollected in tranquillity the triumphs of the previous three-quarters-of-an-hour. Two masterly forced entries (the one through the window being visually of the most dramatic kind), but without a flicker of concern from the world at large, and with never a trace of either crime remaining.

How easy it all had been.

But then I thought, wickedly, why stop there? If it's that easy, why stop at my house and my car?

Mind you, I might have to take the cleaning lady's old man into partnership. I'd have found it difficult to do the car on my own. But the profits should be ample, even divided. An hour on the job, twice or thrice a week—that should be enough. I'll let you know how we get on. □

think a different view may also be tenable and, as we believe is the position with the European Patent Office, our Patent Office must await a case that raises the point before coming to a decision on the facts and arguments adduced.

"As regards sperm or egg-cell modification, the unanswered questions are even more complex since it is also necessary to consider whether methods of surgery or



therapy, which are banned from patentability by Section 4 (2) of the Patents Act 1977, are involved."

In response to a related parliamentary question that I raised, Alex Fletcher, answering on behalf of the Secretary of State for Trade and Industry, claimed:

"The Patents Act 1977 allows patents to be granted for genetically altered micro-organisms and for chemicals they produce. There must be novelty and inventiveness and, unless sufficient information is given to enable the result to be repeated, the micro-organism must be deposited in a culture collection."

I SHALL be interested in the outcome of the Easter visit by Sir Frank Layfield QC to the pressurised-water reactors under construction in France and Belgium. Layfield is in charge of the long-running public inquiry into the Sizewell B project. By contrast the French and Belgians seem to have reached their decisions without much ado.

Is Sir Frank's French good enough to explain to his hosts that he has already been at it for 54 weeks at the Maltings? He returned on 8 May to an agenda of emergency planning, radiation exposure to power workers, and arguments over uranium mining. In France, they believe in doing this sort of thing with technical arguments hammered out by the cotene of graduates of the Ecole Polytechnique. This side of the Channel we do it with lawyers.

DR RICHARD GROVE of the African Studies Centre writes to say that he has received a fairly anodyne reply from Sir Geoffrey Howe to a question on the idea of an International Scientific Zone for the Falklands. Grove says the directors of the Scott Polar Institute, the British Antarctic

Patents, PWR and scientific zones

Tam Dalyell from outside Westminster

THISTLE DIARY



Tam Dalyell MP

in his opinion the phrase 'microbiological process' extended to animal and plant cells when manipulated in tissue culture, and therefore it might reasonably be assumed that a grown culture of such cells would constitute the product of such a process and hence be patentable. Such a product could of course constitute a complete organism. Similar arguments can be applied to arrangements for selecting the sex of an offspring by sperm or egg-cell manipulations, and therefore by analogy the

offspring themselves could arguably be considered patentable."

I brought this matter to the attention of the Department of Trade and Industry, which commented: "The patent law is very much a new one and a practice has not been established to deal with all the various questions that may arise in the microbiological area... The Patents Act 1977 provides in section 1 (3) that: 'A patent shall not be granted... (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such process.' The question, as we understand it, is whether 'product' includes a plant or animal so that, notwithstanding the opening part of (b), a plant or animal is patentable if produced by a microbiological process. The answer to this requires legal interpretation of the Patents Act 1977 and it is not easy to see what this should be. We can understand the quoted view of the examiner in the European Patent Office. However, we

Mr. GORE. Thank you very much. We appreciate your testimony. I will hold up on questions.

We want to hear next from Prof. Samuel Gorovitz from the Department of Philosophy at the University of Maryland.

Professor Gorovitz, you have also assisted us in past inquiries. We are grateful to you for that and we look forward to your testimony.

Please proceed.

STATEMENT OF SAMUEL GOROVITZ, DEPARTMENT OF PHILOSOPHY, UNIVERSITY OF MARYLAND

Mr. GOROVITZ. Thank you, Mr. Chairman.

I am pleased to have an opportunity to speak to you again.

Technologically assisted human reproduction is prominent in the news, but it is not new. Recent events, primarily in other countries, have prompted us to reflect on what our policies should be regarding high-tech procreation. But that has happened before. The dilemmas we now confront, which appear so vivid as we contemplate reports from Australia, France, and Great Britain, are largely problems we have already considered in a systematic way. We may seem to be reacting anew to these recent reports, and in some ways we are, but we must do so in full awareness of the embarrassing history of our own past attempt to deal with this subject matter in the forums of public policy.

Ethical issues center on questions of how people ought to treat one another. Typically, the group of people in question is well defined, but there is dispute about what behavior is justified among or toward them. For example, there is ethical debate about how to treat convicted murderers, about the extent of our obligations toward the poor, about sexual conduct even between consenting adults, about the extent of parental autonomy in the rearing of their children, and so on.

Less often, the debate is clouded by a lack of clear specification of the group in question. For example, the shameful practice of slavery was defended in part by the claim that, although it was not right to treat people as property, those who were enslaved should not be counted as part of the category of people. By this tour-de-force of self-deception, slaveowners could salvage a self-image of decency in their behavior toward other people, while treating people with unconscionable indecency.

The ethical problems raised by atypical reproductive procedures have two dimensions, well illustrated by the debates about embryo transfer. We are not sure what sorts of behavior toward one another are right when it comes to manipulating embryos, partly because we have not decided how much reproductive autonomy people should be allowed, and partly because we have not decided what sorts of entities we want to count embryos as being. These are separate problems. To see that they are distinct, note that there is debate about the propriety of developing sperm separation techniques to allow couples to select the sex of their children, even though the status of the embryo is not at issue, and there is debate about the use of embryos in research, even though reproductive autonomy is not at issue.

Parental autonomy is one of our most vigorously defended values. It is only in the most compelling of circumstances, such as when child abuse is manifest, that we override the normal inviolability of the family, and constrain the behavior of parents. Reproductive autonomy is one of the very few even more deeply entrenched values. We normally consider what others decide to do about having children to be none of our proper business. And if we intrude into this most intimate area of other peoples' lives, their sense of violation may give rise to intense feelings of resentment.

Similarly, we encounter exceedingly strong feelings when we raise questions of where the borders of the morally significant population should be drawn. For some, our treatment of laboratory animals seems comparable to our past failure to acknowledge the moral status of the enslaved. For some, it is the status of the irreversibly comatose that forces the issue. There is even a woman in this area who opposes lawn mowing, claiming it is unjustifiable cruelty toward plant life. Where embryos fall in this array of living creatures is a matter of deep and bitter debate.

We should not be surprised that the debate is unresolved, for it is only recently that we have had much cause to consider the status of embryos as separate entities. Nor should we be surprised that the debate is bitter, for it is compounded by all the emotion that attends attacks on reproductive autonomy.

A decade ago, artificial insemination was available, surrogate motherhood was a possibility, and couples desperate for children sometimes violated social norms in various ways because of their intense desire to participate in the treasured institutions of parenthood and family. But high technology played no central role, and causes of atypical conception, pregnancy, or child acquisition were largely obscured from public view.

The situation is now transformed. Our repertoire of reproductive resources has grown to include in vitro fertilization, egg donation, embryo transfer, and embryo freezing and storage. The range of possible reproductive behaviors has expanded accordingly. What becomes possible tends to be pursued promptly in the quest to overcome infertility, or to circumvent perceived disadvantages in the natural processes of conception and pregnancy. So the new techniques have been put to use, and that use is not obscured from public view.

Instead, the disparate phenomena of a frozen embryo in Australia, a widow in France, and a litigant in England are linked by the news media into a network of highly visible events, fueling public concern around the world that in our effort to gain greater control of our reproductive circumstances, we may be losing control of the values that are most important to us.

We realize with some dismay that our successes in the treatment of infertility have made it possible for embryos to develop into children born a decade or more after the deaths of their biological parents, for women who prefer not to be pregnant to have children who are genetically theirs by hiring other women to be pregnant in their behalf, for embryos to be sold commercially to women who want to become pregnant, for embryos to be created as research materials and grown to an indeterminate stage of development in

the course of experiments, for companies to seek patents on embryo manipulation techniques, and more.

Each of these discomfoting possibilities raises questions of policy of a particularly trying sort, for each of them taps into the deep wells of emotion associated with our convictions about reproductive autonomy and about the status of embryos. Specific questions of law, of the regulation of clinical practice, and of the funding of research stand in need of immediate answers. But fervent hopes and frantic fears infuse the debate, which all too often rests more on rhetoric and non sequiturs than on sober inquiry and carefully reasoned judgment. The problems are compounded by a sense of urgency, as we realize how much faster the pace of scientific progress has become, even as the pace of public policy determination seems to have ground to a halt.

On June 18, 1979, Joseph A. Califano, Jr., then Secretary of Health, Education, and Welfare, published in the Federal Register a report by the HEW Ethics Advisory Board on research involving in vitro fertilization and embryo transfer. That report resulted from over 6 months of study, during which the Board consulted with scholars in reproductive science, ethics, theology, law and the social sciences, and held public hearings throughout the country, taking testimony from private individuals, professional societies, and public interest groups.

The Board comprised a broad spectrum of viewpoints and talents, and its deliberations were sober, thoroughly well informed, and conscientious. The recommendations in the Board's report do not address the full range of issues that have brought us here today, but many of those same issues are addressed. It is instructive to reflect on the fate of those recommendations.

Five years have passed, and the report still sits on the Secretary's desk, awaiting action. Despite the findings endorsed by the board without dissent, the Department has no policy on the cluster of issues it asked the Board to address, and it maintains an unjustified moratorium on all research related to in vitro fertilization or embryo transfer.

In 1978, while the Board was at work, Louise Brown was born. She has since been joined by nearly 600 other children who were conceived in vitro. We are thus in the absurd position of witnesses the growing acceptance of a clinical therapy which we steadfastly refuse to accept as an allowable subject for research, even research into the safety, effectiveness, or improvement of that therapy.

That is embarrassing enough, but the situation is worse. For not only has each Secretary in turn ignored the Board's report, the Department has abolished the board. One consequence of that abolition is that there is no body in place that is an appropriate forum for the pursuit of questions of the sort at issue. Yet, the Department's own regulations require that there be such a body, stating explicitly, "One or more ethical advisory boards shall be established by the Secretary" (45 CFR 46.204a). The Department is thus in clear violation of its own regulations, reaffirmed as recently as last year.

This stark irresponsibility on the part of the administration underscores the need for congressional action in the public interest. What that action should be is foreshadowed in the faded pages of

that 5-year-old report. The Ethics Advisory Board, in 1979, recommended that:

The National Institute of Child Health and Human Development and other appropriate agencies should work with professional societies, foreign governments and international organizations to collect, analyze and disseminate information derived from research—in both animals and humans—and clinical experience throughout the world involving in vitro fertilization and embryo transfer.

Further, the report concludes that:

The Secretary should encourage the development of a uniform or model law to clarify the legal status of children born as a result of in vitro fertilization and embryo transfer . . . Because of the complexity of the legal problems involved in new techniques for human reproduction, the Board recommends that a model or uniform law be drafted that would establish with clarity the rights and responsibilities of donor and recipient "parents," of offspring and of those who participate in the process of reproduction through new technologies.

Had this sound advice been heeded, we might by now be in the process of our colleagues in England, who have before them a comprehensive set of recommendations for a coherent set of policies, which Parliament may now debate. Instead, we continue to have a patchwork of laws and gaps, stigmas, deprivations, uncertainties, confusions, and fears. It is time to find a better way to set public policy regarding controversial dimensions of science and technology. For what we have, as a result of the intransigent inaction of the administration, is simply the status quo ante—not for any sound reason, but, I presume, because it seemed politically safer than adopting any new policy in a morally contested area. Yet that leaves us with an incoherent state of affairs that is good for nobody. It is a response as unproductive as it is cowardly.

The urgency and sensitivity of the issues raised by technologically aided reproduction and by the associated research possibilities, make it mandatory that our deliberations about these issues proceed in an entirely apolitical way. It would be an error, in my judgment, to move directly to the framing of regulatory legislation, perhaps relying on the results of prior studies here and abroad. The issues are too complex and volatile for that to have promise of leading to a stable public policy. Instead, we need an independent agency of reflection and recommendation that is respectful of the full range of sentiment on such matters, and at the same time has the freedom and courage to take the stands that seem most justified—in full awareness that any stand on these matters will draw opprobrium from some quarters.

Congress can, and I believe should, create such a body, charging it to provide for the American people the sort of careful and comprehensive review that was presented to the British Parliament last month by the Warnock Commission. The charge should be similar, to "examine the social, ethical and legal implications of recent, and potential developments in the field of human assisted reproduction," and to recommend public policy as appropriate. But the similarity of scope need not entail a similarity of outcome. Although we are wise to remain informed about the deliberations of other nations, the setting of public policy must be responsive to the needs of our own circumstances, and that requires that we pursue, through independent inquiry, the conclusions that are best for us.

Such an inquiry will have to deal with deep and conflicting convictions, defended with sincere and cogent argument. It will also have to deal, as such inquiries have before, with unrealistic hopes and fears, and with faulty arguments proffered in defense of favored conclusions of all sorts, embraced with little regard for the merits of the case.

As examples of the kinds of substantive issues that will be involved, consider these points:

It will be said that high-technology reproduction is unnatural, that, as Prof. Paul Ramsey has argued, procreation "is certainly one of those 'courses of action' natural to man, which cannot without violation be disassembled and put together again." Yet, much of modern medicine is unnatural in just this way, and we applaud its deliberate intervention in the natural course of events, as we strive to improve our lot. Indeed, nothing is more natural for mankind than just such intervention. So arguments based on an intuitive sense of what is natural will not guide us to sound judgments about what may properly be done.

Mr. GORE. If I could interrupt you there. We have a vote on the floor, and what I want to do is to have a brief recess and then we will come back into session and we will finish up your statement and hear from you, Dr. McCarthy. The recess will only last about 10 minutes; we will reconvene in 10 minutes.

[Brief recess.]

Mr. GORE. The subcommittee will come back to order.

We were in the middle of hearing your statement, Professor Gorovitz, and you were on page 8. We are going to invite you to proceed at this point.

Mr. GOROVITZ. It will be said that technologically reproduction threatens traditional family values by mechanism products and undermining its connection with sexual intimacy. But a very small percentage of the population is in any position to benefit from such procedures. Further, they typically involve hospitalization, surgery, discomfort, inconvenience, uncertainty, and expense. The traditional method, on the other hand, is cheap, can be performed at home, takes little time, training, or skill, and is a great deal of fun. It will remain the method of choice, and atypical reproduction will have little overall impact on the institutions of marriage or the family. So we cannot judge the acceptability of the new processes of procreation simply on the basis of their atypicality and a pessimistic assessment of where they could lead.

It will be said that embryos have the potential to become people, that they deserve respect, that they are not mere tissue or ordinary property, that they are human life. All this is true. But having acknowledged these obvious truths, we still face the task of setting the limits on what is done with embryos, for these truths alone do not entail any simple answers.

Some have hoped to resolve the status of embryos by an affirmation that human life begins at conception. Yet nobody has ever doubted that the human embryo is an instance of human life. Women do not seek embryo implantations because they aspire to give birth to koalas or puppies. All parties to such procedures know that the embryo is human. Nor is there ignorance of the fact that the embryo is alive. It is precisely because of that fact that scien-

tists value the prospect of doing research with embryos. So declaring that human life begins at conception adds nothing to the debate.

There are those who argue, in good conscience, that these procedures should not be allowed. And there are those who argue that they provide welcome new options. This difference of opinion runs deep, and its treatment in public policy debates deserves the most scrupulous intellectual integrity. When something as important as human life is at issue, the public interest is not served by facile slogans about human life.

Anybody deliberating about human embryo transfer will thus face substantial challenges. It will be no easy task to recommend limits on the use and application of the new techniques of human reproduction. About all that is clear is that there must be limits. Every deliberative body which has addressed these issues, in this country, in Australia, and in England, has found widespread public sentiment in favor of setting limits, and has found those sentiments to be grounded in good reasons. But what the limits ought to be remains a matter of debate.

We, too, must now enter that debate in a serious way and must find the limits appropriate to our time and circumstances. Those limits must strike the proper balance between respect for the diversity in our pluralistic culture and respect for the enduring common values that make our culture coherent despite its diversity. They must strike a balance between the attractions of advancing knowledge through research and the need to constrain that advance when it threatens other values as important to us in the value of knowledge. And they must strike a balance between the legitimate desires of those who wish, despite anomalous personal circumstances, to participate in the institution of parenthood, and the legitimate concerns of those who believe that reproductive autonomy must be constrained in the interests of that same institution and of future generations.

Whatever limits are endorsed will seem too stringent to some and too lax to others. Whatever programs are sanctioned will be applauded by some and scorned by others. Deciding which new clinical and research options should be encouraged, allowed, discouraged, or forbidden will require careful separation of the good arguments from the bad, an especially difficult task where intense moral dispute is involved.

But whatever the difficulty of the task and whatever the diversity of opinion about what its outcome should be, the task must be faced if we are to achieve a public policy that follows the path supported by the best reasons, rather than the least public resistance.

The executive branch has had its chance to bring this about, has been urged to do so, and has declined. It is left to Congress to set the matter right.

Thank you.

Mr. GORE. Thank you very much for an excellent statement.

**STATEMENT OF DONALD McCARTHY, DIRECTOR OF EDUCATION,
POPE JOHN XXIII CENTER**

Mr. GORE. Our final witness on this panel and this day and during the 2-day hearing is Dr. Donald McCarthy, director of education at the Pope John XXIII Center in St. Louis. We are delighted you could join us, Dr. McCarthy, and we want to invite you to proceed with your statement at this time.

Mr. McCARTHY. Thank you, Mr. Chairman, ladies and gentlemen.

As the chairman has said, I am from the Pope John XXIII Medical, Moral and Education Research and Education Center that was founded in St. Louis, MO. Our center studies emerging medical moral issues, such as the ones we are discussing, from the perspective of the Judeo-Christian tradition and Catholic teaching.

Because I did my doctorate in philosophy with a doctoral thesis on the philosophical ethics of Bertrand Russell, one of this century's greatest secular humanists, I have some understanding also of medical ethics from a secular humanist perspective.

We have had a long morning today, and I am happy to be the last speaker of the long morning. And my comments are addressed very directly to the embryos as human subjects. Because our panel is concerned about the creation and existence of extra-corporeal embryos, I want to address the embryos themselves, both from a secular and a theist perspective, and I guess I even want to say I want to talk about the embryos as subjects either speaking of the embryo himself or herself because the sex has already been determined.

The center with which I have been associated published its first book in 1976 on the title: *And Ethical Evaluation of Fetal Experimentation* and spent a great deal of time and effort talking about this issue that we have raised in our panel, the dignity and rights of the human embryo. So I would like to focus on that subject.

I would say parenthetically that I don't think any of us in this room would contest the laudable and the heartwarming desires of infertile couples to bring children into the world, especially children of their own genetic heritage. But the ethical problem that concerns me is if we have a good end or a good goal, are there some limitations in the means we use, or even putting it more simply, is it possible that some of our procedures lead us to use embryos as means, and does this involve a form of exploitation?

I would like to offer the statement made by Dr. Robert Edwards, who helped to bring Louise Brown into the world as the first in vitro fertilization child when he described the embryo as a microscopic human being. Microscopic, rather than microcosmic. Microscopic human being, one in its very earliest stages of development. So I am not going to use the term "human person." I will stick with the term "human being," which Dr. Edwards used.

In my acquaintance with scientific fact and sound ethical analysis suggests that Dr. Edwards is correct in calling the embryo, from the point of fertilization, even at its zygote state, a human being.

I think a human being can be described as a distinct individual with a human nature. That is, with material organic elements comparable to those of animals, but with an inherent and an actual in-

herent capacity for spiritual activities, such as inquiring, understanding and making decisions. So the conviction I am expressing is that this human embryo is a distinct individual and has a human nature.

The embryo is a distinct individual from the completion of the fertilization process, when it begins to exist as a single cell of human origin and genotype, and begins to manifest its own self-development with cellular multiplication and differentiation. This development culminates in an adult human being by a continuous dynamic growth if only nourishment and a favorable environment are provided. The embryo even produces a hormone which it sends out to the mother's ovary to insure that the lining of the womb remains in its state of preparation to receive it at implantation.

Now, can we say that this tiny embryo has a truly human nature? Genetics certainly says it is genetically human, but it obviously shows no signs as a single cell zygote of the uniquely human activities that we treasure, such as abstract thought and free decisionmaking. Still if left to develop, the embryo will manifest these very activities. We have every reason to believe it already has the inherent, and I would say the actual capacity for this distinctly human development and for these distinctly human activities.

The fact that the fully human activity is not yet evident does not make the embryo less human. Sleeping adult human beings do not manifest human activities either. The embryo needs time to awaken. Its uniquely human activities are only manifest some years after birth, not even at birth itself.

Science reveals to us only a smooth and continuous unfolding in the life of the embryo throughout gestation. We find no scientific evidence of a threshold or starting point other than fertilization itself for the beginning of human nature. The enigmatic quote of Tertullian, a famous third century scholar in church, "The one who will be a man is already one" summarizes this reasoning.

Now, obviously for some people this thought of an embryo as a living human being verges on the preposterous, particularly because of its microscopic size. Yet upon reflection, we have no evidence that the embryo is any other kind of being, such as a koala bear. Does it not deserve at the very least the benefit of the doubt?

Catholic teaching points this out in a strong statement "Even if a doubt existed concerning whether the fruit of conception is already a human person, it is objectively, that is in a real sense, a grave sin to dare to risk murder."

So we now ask the question, "How should a society committed to human dignity and rights treat this human embryo?" We ask the rhetorical question, "Can one parcel out human dignity and rights according to the months of gestation?" Sound reasoning, based on scientific fact, forces us to accord the embryo full human dignity, in my judgment, and whatever rights accompany it. In other words, I don't see how the embryo can be given partial human dignity any more than the embryo's mother can be partially pregnant.

These reflections that I have been reviewing do not arise from religious faith or Biblical sources, so one cannot object to developing a statement of human rights for embryos on these considerations that I have just offered. However, the right to life of human embryos now goes unprotected in the United States since January

22, 1973; therefore, it may seem futile to discuss further other rights of the embryo such as, for example, the right to be free of nontherapeutic experimentation or the right to have parents who are united in marriage.

But nonetheless, I think many advocates in our society of legalized abortion regard abortion only as a last resort and wish, as far as possible, to respect and treasure the rights and the life of human embryos. The tragic conflicts which are said to justify abortion can hardly be raised in our discussion today of extra-corporeal embryos which only came into existence after great expense and great planning.

So the second part of these comments begins to focus on this notion of rights of extracorporeal embryos. Because these extra-corporeal embryos generated in a laboratory have come into existence through unique modern scientific skills, its unique and critical right is freedom from experimental manipulation or exploitation.

I have a quote "here from the Charter of the Rights of the Family," which was published last year by the Holy See of the Catholic Church. In article IV, there is the simple statement, "Respect of dignity of the human being excludes all experimental manipulation or exploitation of the human embryo." I think that is our concern in this committee, what qualifies for experimental manipulation or exploitation of human embryos?

By exploitation in general, we mean using a human individual as a means primarily for other persons' benefits. The discussion we have had here in this room about ownership of embryos, as well as the Australian discussion about ownership of frozen embryos, highlights the question of exploitation. The ability that we have to produce human embryos in a laboratory automatically introduces the notion in our scientific jargon of quality control. The discussion of embryo wastage indicates that there is an exploitative character in at least some laboratory programs.

I am asking the question, should we not treat every human embryo as if it might, he or she might, grow up to be President and can we not apply the golden rule, "Do unto human embryos what you would want done unto you?" This would mean respecting the principle of human autonomy and informed consent. It would mean that the only kind of risk or invasive procedure that may be ethically justified in being imposed on a human being without informed consent, which is obviously not possible from an embryo, is a therapeutic procedure that is aimed primarily at benefiting that individual; namely, that human embryo.

Now, another whole discussion could be raised, and I am happy to at least raise it, the right of an embryo to an unimpaired sense of identity by being born the true child of a married couple. We all recognize that many children are born out of wedlock, but that frequent violation does not eliminate the right or the notion of the right or our social concern for the right.

I think our Nation and other nations have for centuries given clear recognition to the family, that is to married couples and their children, and this recognition flows from justice, that out of justice, the child to be conceived should be brought into existence in the context which best supports the child's individuality, responsibility, and sense of identity. And we recognize that stable families provide

that context, even though unfortunately countless children are deprived of it, but this is the reason that we have a longstanding traditional effort to discourage illegitimacy.

Now, the same values of the unified family with married parents are jeopardized to some extent in the artificial forms of conception that we are discussing in this committee. I don't think the right of an embryo to belong to a family can be predicated on the sad state of family life that we frequently find in our United States today and the disintegrating instances of family life.

But I think rather the more appropriate approach is to ask the question, Do we have a right to use scientific planning to deny the child's right to its own married parents? Countless children are denied that right by the fortuities of human, modern social life, but put another way here, should our society cooperate through its scientific community in further undermining the family or in further denying the right of a child to married natural parents?

Can we prove from any data that in vitro fertilization from unmarried parents or that the triangle involved in surrogate parenting will further weaken family life? The data for this is not yet available. The point I am making is that such children have been deprived deliberately and with full awareness by all concerned of having both natural parents married to each other.

It is true that adoptive homes are often more loving than the homes of natural parents, but that, again, does not annul the basic right of the child to natural parents, first of all, and if we are bringing children into the world through a technological procedure, it seems to me there is reason to respect this right of a child to his or her natural parents. In other words, I think there is good reason for saying that our society ought not collaborate in the injustice of deliberately depriving children of their natural parents.

Now, these reflections, of course, would even suggest the exclusion of male donors of semen or female donors of ovum. Artificial insemination of wives by donors' sperm is already in use in this country. The judgment as to whether legislation should restrict this practice or what might be done about the ethical or moral dimensions of this practice can be kept separate from our discussion today.

As I understand it, we are primarily concerned not about artificial insemination, but about human embryos, and we are concerned about the way in which human embryos are involved, in particular the lavage procedure of surrogate parenting, if we want to call it that, that Dr. Buster described and, of course, the question of in vitro fertilization. And I am raising here the point of in vitro fertilization from unmarried donors of semen and sperm.

I am going to suggest what I would call possible areas of legislative action or of guidelines, what Dr. Gorovitz raised, the question of what would be appropriate limits? I am going to make a few suggestions in closing, at least suggestions as to how we might deal with what seems to be the more serious ethical issues relating to extracorporeal embryos.

But, in closing this little discussion of the rights of extracorporeal embryos, I want to appeal to our American tradition. We are committed in our democratic heritage to protect the life and rights

of the weakest and most helpless members of society, and I think embryos are members of our society.

We do live in an imperfect world marred by many forms of injustice, discrimination, and needless suffering. The point I would be contending is that the class of human embryos who were under discussion today, those generated in a laboratory or generated in a surrogate mother with possible lavage or flushing out and reimplantation, do have civil rights which need protection; that in a free and democratic society, we are called upon as responsible citizens to work for those rights rather than to acquiesce in technological violations of them.

This brings me to these concluding comments or suggestions or possible forms of guidelines, and I am not going to enter into the very practical discussion of how such guidelines should be implemented. But I do want to suggest six of them.

First of all, legislation or guidelines could and I believe should prohibit any form of experimentation on a human embryo which is likely to damage that embryo or to delay its natural development by delaying the time of its transfer and implantation. Only procedures intended to benefit the embryo should be allowed according to the ethical principle that we do not do unconsented experimentation on human subjects.

Second, any form of freezing of human embryos could, and I would suggest should, be excluded. The long-term risks of such freezing of human beings are still unknown, but even without risk, to subject human embryos to freezing, without their consent which is obviously unobtainable, violates the dignity of the embryo unless the freezing represented a proven kind of therapeutic procedure necessitated by the embryo's condition of health and make the analogy that we would not think of freezing perfectly healthy human babies after birth, so I see no genuine and ethically persuasive reason for freezing perfectly healthy human embryos.

Third, any deliberate taking of the life of an extra-corporeal embryo should be prohibited as well as any neglect of reasonable efforts to implant such an embryo in its mother's body. The legalization of aborting fetuses and embryos in our present legal situation does not of itself entail the legalization of destroying extra-corporeal human embryos or failing to implant them.

Dr. Walters made the point that we don't countenance it as buying and selling human embryos. He made the point that we compare their human dignity to that of human cadavers or human organs. But obviously from what I have been saying, I would find a dignity in a living human embryo that would be transcendently superior to that of a cadaver or simply of an organ.

The fourth point I would make is that removal of an inviable fetus or embryo from its mother's body for transfer to another woman, the lavage procedure, could and should be prohibited by statutory definition as a form of experimental manipulation unless necessary to save the life of the fetus or the embryo. And if we cannot agree that it is a form of experimental manipulation, we might be able to agree that it is a form of exploitation of this tiny human being.

The fifth point I would make is that it would seem that statutes could and should insist that *in vitro* fertilization procedures unite

only sperm and ova of married couples out of respect for the embryo's right to natural parents, and that point has been discussed today. The deliberate surrogate arrangement in which a woman brings to full term an infant she conceives from sperm of a married man for him and his wife also violates the rights of that child to natural parents as do all forms of artificial insemination with donor gametes and all forms of extramarital parenting.

We have made reference to all of these present situations. If the law tolerates these situations, that does not remove the inherent injustice to which I am pointing any more than legal toleration of other forms of injustice, or discrimination removes the injustice or the discrimination. But I am simply not making recommendations about these latter practices, the practices of the artificial insemination, with donor gametes or even the surrogate parenting when the infant is brought to term.

The sixth point that I would refer to is that out of respect for the human embryo's rights, I believe the law could and should readily prohibit any parthenogenetic or uniparental procreation by cloning or any human-animal hybridization. No group of adults would seem to have the right to generate a human being by such procedures which include, of course, among other objectionable features, the deprivation of two natural parents for that human being if indeed it is a human being which results.

Now, these six kinds of legislative protection or these six kinds of limits or guidelines to our manipulation of extra-corporeal embryos could be supported and presented as a kind of civil rights platform for the minority rights of these tiniest human beings, using again Dr. Edward's own language describing the tiny human being, "The embryo as a human being, a microscopic human being." I don't think these six recommendations that I have mentioned would eliminate all violations of the embryo's rights to its own natural parents. We know that every human being will not have its own natural parents, but I think at least these kinds of recommendations are desirable on the thesis that some protection is better than none at all.

As a matter of fact, there are many serious ethicists, myself included, who believe that the technique itself of in vitro fertilization violates the rights of human embryos from another perspective, on the ground that human beings have a right to be conceived in an act of personal self-giving and conjugal love rather than through a series of technical acts in a sterile laboratory, but that is another discussion which I am not engaging here.

I would rather conclude with the reminder that childless married couples suffering from infertility do deserve public support in their laudable efforts to become parents which do not violate the civil rights of embryos. I refer to improved techniques for opening blocked fallopian tubes to the possible successes of ovum transfer from the mother's ovary beyond the tubal blockage, but it is the mother's own ovum, and it remains in the mother's body. That is a procedure being pioneered in Ohio by Dr. David McLaughlin, but it is not the transfer of a fertilized ovum, but of an ovum awaiting fertilization.

I refer also to efforts at transplanting ectopic embryos into the uterus which will be available, as I see it, in the years to come. So

this whole discussion of embryo rights may have sounded like a tempest in a test tube, but I have been presenting, from at least one perspective, an ethical evaluation of these remarkable new capacities we have discussed this morning to dominate human lives.

The more remarkable the capacity, the more urgent the need for ethical reflection and for an honest pursuit of life and liberty as well as happiness for our embryonic sisters and brothers, any one of whom may be President some day.

[The prepared statement of Donald McCarthy follows:]

PREPARED STATEMENT OF DONALD MCCARTHY

My name is Donald McCarthy and I am a Catholic priest of the Archdiocese of Cincinnati. For the past five years I have served as Director of Education of the Pope John XXIII Medical-Moral Research and Education Center in St. Louis, MO. Our Center studies emerging medical-moral issues for the perspective of the Judaeo-Christian tradition and Catholic teaching. Because I did my doctorate in philosophy with a doctoral thesis on the philosophical ethics of Bertrand Russell, one of this century's greatest secular humanists, I have some understanding also of medical ethics from a secular humanist perspective.

I wish to address the ethical questions related to the creation and existence of extra-corporeal embryos from both a secular and a theist perspective. My remarks will conclude with some recommendations for public policy in our nation. The first book which our Center published, "An Ethical Evaluation of Fetal Experimentation"¹ in 1976 studied the issue of the dignity and rights of the human embryo in depth. I will first summarize that research and then apply it to extra-corporeal embryos.

(1) The Dignity and Rights of the Human Embryo:

The convictions of science and philosophy about the human embryo which I find coherent and convincing are summarized in the description offered by Dr. Robert Edwards, who helped bring Louise Brown into the world: The embryo is "a microscopic human being—one in its very earliest stages of development."² In this discussion I will avoid the term "human person" and stick with the term "human being" which Dr. Edwards used.

My acquaintance with scientific fact and sound ethical analysis demonstrates that embryos should rightfully be called "human beings," a human being can be described as a distinct individual with a human nature, that is, with material and organic elements comparable to those of animals and with an inherent capacity for spiritual activities such as inquiring, understanding, and making decisions. The embryo is a distinct individual and has a human nature.

The embryo is a distinct individual from the completion of the fertilization process when it begins to exist as a single cell of human origin and genotype and begins to manifest its own self-development with cellular multiplication and differentiation. This development culminates in an adult human being by a continuous dynamic growth if only nourishment and a favorable environment are provided. The embryo even produces a hormone which it sends out to the mother's ovary to ensure that the lining of the womb remains in its state of preparation to receive it.

But does the embryo have a truly human nature? Genetics will tell us that it is genetically human. But it obviously shows no signs, as a single cell zygote, of uniquely human activities like abstract thought and free decision-making. Still, if left to develop, the embryo will manifest these activities. We have every reason to believe it already has the inherent capacity for distinctly human development and distinctly human activities. The fact that fully human activity is not yet evident does not make the embryo less human. Sleeping adult human beings do not manifest human activities either. The embryo also needs time to awaken; its uniquely human activities are only manifest some years after birth.

Furthermore, science reveals only a smooth and continuous unfolding in the life of the embryo throughout gestation. We find no evidence of a threshold, a starting point other than fertilization itself, for the beginning of human nature.

The enigmatic quote of Tertullian, a famous third century scholar in the Church, "The one who will be a man is already one,"³ summarizes our reasoning.

¹ Edited by Donald G. McCarthy and Albert S. Moraczewski O.P. (St. Louis, MO, The Pope John Center, 1976).

² Robert Edwards and Patrick Steptoe, *A Matter of Life*, London, 1981, p. 101.

³ *Apologeticum*, IX, 8 PL 1, 371-72.

Obviously, for some people, the thought of the embryo as a "human being" verges on the preposterous. Yet, upon reflection, we have no evidence that the embryo is any other kind of being. Does it not deserve, at very least, the benefit of the doubt? Catholic teaching points this out in the strong statement, "Even if a doubt existed concerning whether the fruit of conception is already a human person, it is objectively a grave sin to dare to risk murder."⁴

Hence we ask the question, how should a society committed to human dignity and rights treat the human embryo? Can one parcel out human dignity and rights according to the months of gestation? Sound reasoning based on scientific fact forces us to accord the embryo full human dignity and whatever rights accompany it. I do not see how the embryo can be given partial human dignity any more than the mother can be partially pregnant.

These reflections in no way arise from religious faith or Biblical sources. Hence one cannot object to developing a statement of human rights for embryos on these considerations. However, the right to life of human embryos now goes unprotected in the United States since January 22, 1973. Hence it may seem futile to discuss further such rights of the embryos as the right to be free of non-therapeutic experimentation or to have parents who are united in marriage.

Nonetheless, many advocates of legalized abortion regard abortion only as a last resort and wish, as far as possible, to respect the life and rights of human embryos. The tragic conflicts which are said to justify abortion can hardly be raised in discussing extra-corporeal embryos which only came into existence after great expense and planning.

(2) The Rights of Extra-Corporeal Embryos:

Because the extra-corporeal embryo generated in a laboratory has come into existence through unique, modern scientific skills, its unique and critical right is freedom from experimental manipulation or exploitation.⁵ By exploitation we mean using a human individual as a means primarily for other persons' benefit. The recent discussion about "ownership" of frozen embryos in Australia highlights the issue of exploitation. The ability to produce human embryos in a laboratory automatically introduces the notion of "quality control" in test tube fertilization. The discussion of embryo "wastage" indicates the exploitative character of some laboratory programs.

Instead, should we not treat every human embryo as if it might grow up to be President? Can we not apply the Golden Rule, do unto embryos what you would want done unto you? This would mean respecting the principle of human autonomy and informed consent. The only kind of risk or invasive procedure one may be ethically justified in imposing on a human being without informed consent is a therapeutic procedure aimed primarily at benefitting that individual.

Another major kind of embryo right is the right to an unimpaired sense of identity by being born the true child of a married couple.⁶ Of course, many children are born out of wedlock, but the violation of this right does not eliminate it from our concern. Our nation and other nations have for centuries given clear recognition to the family, i.e., a married couple and their children. This recognition flows from justice—out of justice to child-to-be-conceived should be brought into existence in the context which best supports the child's individuality, responsibility, and sense of identity. We recognize that stable families provide that context, even though countless children are deprived of it. Hence, our long-standing, traditional efforts to discourage illegitimacy. The same values are jeopardized, however, in artificial forms of concept which this committee is now scrutinizing.

Our point in this discussion of the right to a family does not rest on the often sad state of family life in the United States today. Rather it rests on this issue: Do we have a right to use scientific planning to deny the child's right to its own married parents? Put in another way, should our society cooperate through its scientific community in further undermining the family?

The debate at this point may turn to scientific data. Can we prove that IVF from unmarried parents or surrogate parenting will further weaken family life in Amer-

⁴ *Declaration on Abortion* by the Sacred Congregation for the Doctrine of the Faith, Nov. 18, 1974. Published by U.S. Catholic Conference, 1312 Massachusetts Ave, N.W., Washington, D.C. 20005.

⁵ Cf. Article 4, part b, of the *Charter of the Rights of the Family*, published in Rome by the Holy See, Oct. 22, 1983: "Respect of the dignity of the human being excludes all experimental manipulation or exploitation of the human embryo."

⁶ Cf. *In Vitro Fertilisation: Morality and Public Policy*, statement by the Catholic Bishops' Joint Committee on Bio-Ethical Issues on behalf of the Catholic Bishops of Great Britain, 1983, #16-18.

ica? The data is not yet available, but what is clear is that such children have been deprived, deliberately and with full awareness by all concerned, of having both parents married to each other. True, adopting homes are often more loving than the homes of natural parents, but the rights of children are to natural parents first of all. Our society ought not collaborate in the injustice of deliberately depriving children of their natural parents.

These reflections about a child's right to married parents would even suggest the exclusion of male donors of semen or female donors of ovum for purposes of conceiving new life without one's marriage partner being the fully natural parent. Artificial insemination of wives by donor sperm is already in use in this country. The judgment as to whether legislation should restrict this practice can be kept separate from the question we are considering here today: actual surrogate parenting and the IVF generation of human embryos from the gametes of unmarried persons. These latter questions are far more serious than those of donor semen or donor ovum.

In concluding remarks I will discuss possible areas of legislative action to meet only the more serious issues in surrogate parenting and IVF.

However, to conclude this discussion of the rights of extra-corporeal embryos let me appeal to our American traditions. We are committed in our democratic heritage to protect the life and rights of the weakest and most helpless members of society. We live in an imperfect world marred by many forms of injustice, discrimination, and needless suffering.

I contend that the class of human embryos who are under discussion today—those generated in a laboratory or those generated in a surrogate mother for flushing out and reimplantation in another woman—have civil rights which need protection. In a free and democratic society we are called upon as responsible citizens to work for those rights rather than to acquiesce in technological violations of those rights.

(3) Protecting the Rights of Extra-corporeal Embryos:

A number of specific kinds of legislative protection would at least partially protect the rights of human embryos discussed here.⁷ I will offer six suggestions.

(1) First of all, legislation could prohibit any form of experimentation on a human embryo which is likely to damage that embryo or to delay its natural development by delaying the time of its transfer and implantation.

Only procedures intended to benefit the embryo itself should be allowed.

(2) Secondly, any form whatever of freezing of human embryos could be excluded. The long-term risks of such freezing are still unknown. But even without risk, to subject the embryo to freezing without consent violates the dignity of the embryo unless freezing represented a proven kind of therapeutic procedure necessitated by the embryo's condition of health. We would not think of freezing perfectly healthy babies after birth, so I see no genuine and ethically persuasive reason for freezing perfectly healthy embryos.

(3) Thirdly, any deliberate taking of the life of an extra-corporeal embryo could be prohibited as well as any neglect of reasonable efforts to implant such an embryo in its mother's body. The legalization of aborting fetuses and embryos does not entail the legalization of destroying them extra-corporeally or failing to implant them.

(4) Fourthly, removal of an inviable fetus or embryo from its mother's body for transfer to another woman could be prohibited by statutory definition as a form of experimental manipulation unless necessary to save the life of the fetus or embryo.

(5) Fifthly, it would seem that statutes could insist that in vitro fertilization procedures unite only the sperm and ova of married couples out of respect for the embryo's right to natural parents. The deliberate surrogate arrangement in which a woman brings to full term an infant she conceives from the sperm of a married man for him and his wife also violates the rights of that child to natural parents, as do all forms of artificial insemination with donor gametes and all forms of extramarital parenting. If the law tolerates such actions, that does not remove the inherent injustice, any more than legal toleration of other forms of discrimination.

(6) Sixthly, out of respect for the embryo's rights the law could readily prohibit any parthenogenetic or uniparental procreation by cloning or any human-animal hybridization. No group of adults would seem to have the right to generate a human being by such procedures which include among other objectionable features the deprivation of natural parents for that human being (if indeed it were a human being).

These six kinds of legislative protection for extra-corporeal embryos could be supported as a kind of civil rights platform for the minority rights of the tiniest human beings. As indicated, they would not eliminate all violations of the embryo's rights

⁷ Cf. *ibid.* No. 10-15.

to its own natural parents. But they are desirable on the thesis that some protection is better than none at all.

As a matter of fact, many serious ethicists, myself included, also believe that the very technique of in vitro fertilization violates the rights of human embryos on the ground that they have a right to be conceived in an act of personal self-giving and conjugal love rather than through a series of technical acts in a sterile laboratory. That discussion must be tabled for now, though.

Let me conclude with the reminder that childless married couples deserve public support in their laudable efforts to become parents which do not violate the civil rights of embryos. I refer to improved techniques for opening blocked fallopian tubes, to the possible success of ovum transfer from the mother's ovary beyond the tubal blockage,⁸ and even to efforts at transplanting ectopic embryos into the uterus.⁹

This discussion of embryo rights may have sounded like a tempest in a test-tube! But we have sought to offer ethical evaluation of remarkable new capacities to dominate human lives. And, the more remarkable the capacity, the more urgent the need for ethical reflection and the honest pursuit of life and liberty as well as happiness for our embryonic sisters and brothers, any one of whom may be President some day!

BIOGRAPHICAL SKETCH

Rev. Donald G. McCarthy is a priest of the Catholic Archdiocese of Cincinnati. He holds a Ph.D., philosophy from the University of Louvain, Belgium, and in 1972-73 did a Residency in Theology and Medical Ethics at the Institute of Religion in the Texas Medical Center at Houston.

Since 1973 he has served as a resource person and lecturer for conferences in the field of medical ethics. He was elected to the Board of the Pope John Medical-Moral Research and Education Center in December 1977. He moved to St. Louis in August, 1979 to accept the position of Director of Education at the Pope John Center. In August, 1984 he returned to Cincinnati to become pastor of St. Antoninus parish, but he continues to serve the Pope John Center as Senior Educational Consultant.

He is a member of the American Society of Christian Ethics, the Catholic Theological Society of America, and the Institute for Theological Encounter with Science and Technology. He was a professor at Mount St. Mary Seminary in Cincinnati from 1960-79 and director of the Newman Center at the University of Cincinnati from 1960-69.

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Editor, *Beginnings of Personhood* (Institute of Religion, 1973).

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Co-editor with Albert Moraczewski, O.P., *An Ethical Evaluation of Fetal Experimentation* (Pope John Center, 1976).

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⁸ Cf. "Should Catholic Hospitals Encourage Low Tubal Ovum Transfer?" in *Hospital Progress*, (journal of the Catholic Health Association), St. Louis, MO, Mar., 1984, pp. 55-56.

⁹ Cf. Sept., 1984, issue of "Ethics and Medics", monthly four-page newsletter of the Pope John Center, 4455 Woodson Rd., St. Louis, MO 63134.

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Mr. GORE. Thank you very much. I appreciate your testimony.

Let me begin with you, Dr. McCarthy. You were here yesterday,
 were you not?

Mr. MCCARTHY. I am sorry, I wasn't.

Mr. GORE. Are you familiar with the testimony at all?

Mr. MCCARTHY. No.

Mr. GORE. During some of the testimony yesterday, I asked mem-
 bers of one panel about the possibility that in making some of
 these ethical judgments, many doctors and scientists seemed at
 times to me to be assigning zero value to any rights of the embryo.
 There was a dispute about that, but it was a line of questioning in
 which I engaged.

Let me turn that around in beginning questions for you. It seems
 to me at times you come close to assigning no rights, when there is
 a conflict between the desire or right, if you see one, of prospective
 parents to give birth and the rights of the embryo. A lot of times
 these judgments are difficult and subtle. At times you seem to
 come close to assigning zero value to the rights of childless couples
 to have a child by use of one of these new techniques.

Is that unfair? Do you see what I am getting at?

Mr. MCCARTHY. I think I do, Mr. Chairman, and I deliberately
 didn't bring up the question that you have just mentioned, the
 question of the rights of parents to have a child. I am very doubtful
 whether I could support the right of parents to have a child. It is
 going to take some analysis to decide how we might base that
 right.

Certainly the vision I have of human life and marriage and
 human sexuality would be that married couples clearly have a
 right to procreative activity, but whether the child will result from
 that activity is, it seems, more difficult to me to say that they have
 a right to make that procreative activity successful. Maybe that is
 particularly in a theistic perspective, if God is the author of human
 life, maybe I would be a little bit less inclined to assert the right to
 have or make a child than one who did not adopt a theistic per-
 spective.

Mr. GORE. Well, I was correct in my surmise then, that you do come close to assigning a zero value to that?

Mr. McCARTHY. I think the Supreme Court made a reference to the right to conceive and bear a child. But I wouldn't be satisfied that that would establish that right within itself.

Mr. GORE. Without getting into a legalistic discussion of it, it does seem to me that such a right does exist. There is my own personal opinion now. How it is balanced against the rights of an embryo brought into existence is another question, and an infinitely more difficult question.

Mr. McCARTHY. Mr. Chairman, just as an interjection, I would be uncomfortable saying we have a right to health, but I think we have a right to health care. So there is a little bit of an analogy there. I don't think we have the right to have a child, but we have a right to those procedures that are in our possession to generate a child and whether the child is generated or not is beyond our right, I think.

Mr. GORE. Well, for what it is worth, let me just pursue that for a moment. We are accustomed to speaking of life, liberty and the pursuit of happiness in this country in the context of a legal structure, constitutional structure that emphasizes the individual and the rights of individual, many believe there is no greater happiness in this world than giving birth to children and having children.

And when you talk with families, such as those who testified on the first panel this morning, their intense desire to have children and the tremendous joy which children bring does certainly seem to invest the pursuit of children have something very akin to a right, if not an absolute right, certainly nevertheless something that must be weighed heavily when a choice is made which would prevent them from fulfilling or from reaching their goal.

That may be a nonphilosophical way to describe it, but it just seems as we should give some weight to the right of childless couples who want children to satisfy those legitimate desires. You don't agree?

Mr. McCARTHY. Well, I just wanted to suggest that if, for purposes of discussion, you would like to concede to married parents the right to a child, then we still have to face some of the other questions that I raised in the paper. For instance, does the married couple have the right to involve two more people in bringing this child into the world?

And I was making the point that I think there is serious ground for saying that a child has a right to its own parents, to natural parents.

Mr. GORE. You discuss on page 3 and page 4 the right to have parents who are united in marriage, and then on page 4 you go further and you speak of the right identity, unconfused identity. Do you know the passage I am looking for?

Mr. McCARTHY. The bottom of page 4.

Mr. GORE. Yes, the right to an unimpaired sense of identity by being born the true child of a married couple. Those are two different concepts, aren't they? The concept of page 3, the right to have parents who are united in marriage, can be satisfied even with the use of an egg donor or a sperm donor.

Mr. MCCARTHY. I see what you mean. I think I agree with your point that they are two separate points, and I would like to support both of them, that the child has a right to its natural parents and that its natural parents be a married couple.

Mr. GORE. All right.

Now, Dr. Walters, you wrote an article that I read for the Hastings Center where you talk about a whole series of issues that are raised by these alternative reproductive technologies, and you correct me if I am summarizing this in a faulty way. But you seem to say that among all of the issues involved, and, Professor Gorovitz, I invite you and Dr. McCarthy to jump into this as you wish.

You seem to say that among all of the issues that are involved and all of the ethical problems, there are two that stand out above all the rest as threshold bioethical issues that determine how you view all of the others. The first is what is your definition of the embryo? Is the embryo a human being or do you use an Aristotelian definition of a developing and evolving right as the embryo develops? That is the first issue. And clearly you two are in fundamental disagreement with Dr. McCarthy on that question.

The second threshold issue is what value do we as a society place upon the sanctity of the traditional family unit as we know it, husband and wife and a natural child born to that husband and that wife? Then all of the other stuff about the risks of freezing, the duty to screen, all of the other issues seem to be appended to, or at least seem to come after those first two threshold issues.

Have I summarized that aspect of your paper in a fair way?

Dr. WALTERS. If you include within the definition of family the notion of the opportunity to be parents, then I would agree that those are the two most basic questions connected with all of the reproductive technologies and with research involving human embryos.

Mr. GORE. OK. Do you agree with that architecture or hierarchy, Professor Gorovitz?

Mr. GOROVITZ. Yes, indeed, and I think it is mirrored in my own testimony in which I emphasized reproductive autonomy and the status of the embryo as the two primary questions, and it is clear, I think, that these two values described by Dr. Walters are in conflict over some of the issues. That is if we acknowledge a high degree of respect for the traditional family, that itself provides some of the argument in favor of modern technological reproductive techniques which allow people who would not otherwise be able to do so to participate in that kind of institution.

Mr. GORE. Say that again, excuse me.

Mr. GOROVITZ. I am saying that we have here two different questions. The status of the embryo and the status of the family, if you like, the traditional conception of the family. These two different questions have many different combinations of possible answers. If one says I value and respect the embryo as a human living being or entity and also I value and respect the traditional family, it is not clear what follows from those two values.

Indeed, those two values may come into conflict, because it is precisely a valuing of and respect for that traditional sense of a family that inspires many people to seek reproductive technology

so that the motivation to use embryos may arise precisely out of a sense of the importance and value and sanctity of the family.

Mr. GORE. That is why you insisted on a clarification of the definition a moment ago?

Dr. WALTERS. Yes.

Mr. GORE. All right.

Dr. WALTERS. There is a sense in which we are talking about extended families very early on in cases of necessity. If one member of a couple can't produce fertilizable eggs or a sperm that are capable of fertilizing the eggs in the spouse, then that couple has no recourse but to go outside the family to be an extended family, so to speak, if they want to have children that are as nearly their own as possible.

Mr. GORE. All right, but Dr. McCarthy would frame this second value or issue in a different way, and you do speak of the sanctity of the family in a way that would exclude the use of a third party, a third person in the process of procreation because of the value he places on having a man and a wife united in marriage, both of whom are the natural parents of the child. That is the definition of the family he uses and how important you believe that is determines your view of many of these other issues.

Do you think this is a helpful way to structure this?

Mr. MCCARTHY. Yes, I feel we are getting some further clarification out of all of this, and the immediate comment I wanted to make was in line with the term we just used about extended family. It opens up all sorts of thoughts. You can go back to Biblical notions of polygamy, for instance, and see if there is some kind of analogy between the wife who obtains the new tiny embryo from another woman, some analogy between what happened among the patriarchs of the people of Israel.

The response I would like to make to all of this is not to sit in judgment on polygamy and monogamy, because that takes us far afield, but my response is to go back to the kind of perspective I presented, which seems to me to be most cogent.

If we, as a collective community with our scientific planning, are going to bring human embryos and human children into the world, do we bring them into the world in a quasipolygamous context, if we refer back to ancient times, or if we are bringing them into the world, do we respect what can be argued to be very basic rights, the right to natural parents and the right to married parents?

My point is that, without getting into discussions of alternate family styles and polygamy and so forth or different kinds of triangular arrangements of parents, we can bypass all that discussion by simply asking if we are going to respect these human embryos, what kind of rights should we concede to them?

As I am presenting their rights, they have a right to their own natural parents who are married, as opposed to other variations on that theme.

Mr. GORE. I want to turn to you, but I want to draw an analogy first. Courts have in several cases prohibited research into or have prohibited the electronic eavesdropping of the deliberations of juries, even if the court knew about it ahead of time; in the jurisdictions where it was done, it was justified on the grounds that we

could learn a great deal sociologically about how 12 people arrive at a determination of guilt or innocence.

But courts have said no, that can't be done because it violates the sanctity of the jury as a forum, and their deliberations as a process, and the knowledge gained therefrom would inevitably be used to jigger the deliberations of future juries.

Dr. McCarthy, your view of research and intervention into this area seems to be similar in that the value you place on the traditional procreative family is such that you just don't want any intervention or tinkering with it at all to speak of?

Mr. MCCARTHY. Well, there are two points I would like to make in response to that. Let's take the second one first, about what kind of intervention could be recommended.

Mr. GORE. Yes.

Mr. MCCARTHY. Certainly there are therapeutic interventions to overcome infertility, and we are just on the threshold of new developments. I don't know if our physicians that have testified have discussed this, but surely there are many new possibilities for overcoming the infertility we have been talking about and surely that, we can all agree, is an extremely desirable direction to go, whether it means replacing fallopian tubes, opening the blocked tubes, bypassing the blocked tube and getting the ovum below it, whatever method we can use. Certainly that is going to be highly desirable.

Secondly, in terms of we, as a society, what else we should do, in those comments that I made, I was not ruling out the present practices of artificial insemination from donors and even the present possibility of the woman carrying to term, but I would have objections to them on principle. But I am not making recommendations for statutory control of those policies. I want to make that point.

Mr. GORE. I was just exploring your thought system.

Mr. MCCARTHY. I want to make another point quickly.

You mentioned the sanctity of the witness process. I didn't use the term "sanctity of life" in the comments today because I realize it has religious overtone.

Mr. GORE. Sanctity of the family?

Mr. MCCARTHY. I didn't use the term "sanctity of the family" even, and I tried very hard to stay with the term dignity because it is a secular term and it is so closely related to our whole concept of dignity and rights. But obviously I would be happy to speak about the sanctity of the family too.

Mr. GORE. I appreciate your testimony.

Professor Gorovitz, you wanted to speak?

Mr. GOROVITZ. Two separate points, one raised by your reference to the Wichita jury tampering experiment. I think the reasons for the prohibition of jury tampering research really have to do not with the sanctity of the jury process in some inexplicable or inherent sense, but rather the conviction that to allow a process of oversight of juries at work while they are at work can modify the ways in which they work in the future.

That is, jurors who are not secure in their knowledge that their transactions are private may behave differently. They may fear re-creminations. They may feel constraints, legitimately or not, that will eliminate the freedom that juries have long enjoyed to make judgments as they see fit on the merits of the case.

Mr. GORE. It seems to me the analogy still holds. I won't torture it, but go ahead.

Mr. GOROVITZ. It is not clear to me that the analogy does hold here. I think that the claim can be made that the natural family and natural procreative processes are optimal, but where they are not possible, we then ask what is the next best position?

Mr. GORE. Yes.

Mr. GOROVITZ. The policy argued by Dr. McCarthy seems to be the next best position is to accept perhaps with profound regret that one involved in such situations will not have the opportunities for which one might have hoped. The position which others are arguing is that there is no adequate reason not to allow people to pursue interventions which will be corrective and which, while they are not exemplifying the ideal state of affairs, are still exemplifying a preferable state of affairs.

But I want to shift now to the other point that I think is more pervasive, and that is what distresses me perhaps most in all of this discussion, and in your remarks as well as in Dr. McCarthy's, is the constant recourse to the notion of rights as the appropriate moral category. I think that we mislead ourselves if we frame these questions as if what is at issue always is a question of rights.

I think cadavers have no rights. But I think it is wrong to do certain things to and with cadavers, not because we violate their rights but for other kinds of reasons.

Similarly, I think there are behaviors that are wrong in respect to embryos, but it is not the case that the only justification for that position is that it violates purported rights that they have. I am not prepared to concede that embryos can reasonably be described as having rights. I don't believe that that is the only basis for granting them moral significance, and I am a little discomforted by the framing of the question when you say, should we not take into account the rights, the reproductive rights of the infertile couple and weigh them against the rights of the embryo?

I think there is a prior question and that is, is it the best public policy to grant rights to those morally significant entities that we call embryos? And that is a very difficult question. I have heard no convincing argument that embryos have any rights at all. I have heard lots of convincing arguments that embryos have moral significance, and that there are moral reasons to be cautious in respect to our behavior in regard to them. So I would like to broaden the moral categories.

Mr. GORE. Well, if a child is born and suffers from a birth defect that is sustained while it was an embryo, it has a right to recover damages as a result of that injury.

Mr. GOROVITZ. Right.

Mr. GORE. That is a right that exists in the embryo.

Mr. GOROVITZ. That is a right that exists in the child. It doesn't follow from that that right existed in the embryo at the time it was an embryo.

My concern with that kind of argument is a bit analogous to the golden rule appealing. That is, to ask what would I have preferred had I been the embryo in question? I think the answer is clear. Had I been the embryo in question, I would not have been the sort of thing that could have preferences, values, aspirations. The fact

that I now have preferences retrospectively, it is certainly my view that I am pleased that my parents did not have an abortion.

Mr. GORE. If I remember the line of cases correctly, in fact, no court has allowed a cause of action unless the birth has already taken place for damages in utero. If I am not mistaken, that is a distinction in law, but it just seems to me that the use of the word "right," while problematic, your objections to the use of the word "right," I understand it, but yesterday we substituted the word "protection," society's protection to the embryo.

It seems to me a fine line of distinction. It is a useful shorthand. Maybe it obscures, but it doesn't for me to speak of rights.

Mr. GOROVITZ. My concern is not that it obscures but that it has, as I see it, potentially pernicious consequences. We see a subtle line of reasoning, which begins with the point that I argued in my testimony that is acknowledged by all partisans all around that the embryo was human, that the embryo was alive; therefore, the embryo was human life, that it is an entity or being, it is therefore uncontestably a human being.

That is purely descriptive. Nothing follows from that about what we ought to do, but the argument then proceeds by a subtle trading on the connotation and the cache of the notion of a human being.

Mr. GORE. At what point does it have rights? You are saying that that is distinct from a determination of at what point is it a human being?

Mr. GOROVITZ. That is right. And in the acquisition of rights, we must be very careful about thinking that if we acknowledge that it has certain legitimate interests or rights, it directly follows that it has the full package. So when we talk about civil rights and minority rights and so on, I think we have been victimized by an early choice of language which carries with it more than the warrant of the case.

Mr. GORE. I know Dr. McCarthy disagrees strongly with that. I want to know what you feel about it, Dr. Walters. Is the use of the word "right" inappropriate in your view in this context?

Dr. WALTERS. My preference is to talk about the kinds of obligations that we who are undoubtedly persons do have to these early entities rather than to talk about the rights of embryos. I think protections is a reasonable compromise. Perhaps the right language comes primarily from the legal context, rather than the ethical context.

Mr. GORE. Professor Gorovitz, you seem to say in your disagreement that prospective parents have a right to satisfy their desire to have children. You don't think the word "right" is appropriate there either?

Mr. GOROVITZ. I think it is much more appropriate there. Oh, yes, there I think we are talking about entities which are undeniably people with all that that entails, creatures with histories of the development of outlooks on life, with life plans, with aspirations, with psychological dispositions, with attitudes. We are talking about just the sorts of entities which exemplify the bearers of rights.

So I have no misgivings about talking about the rights of parents to pursue their procreative aspirations. I don't think it follows from that that it is clear what the limits for those rights. We say, for

example, that parents do not have the right to purchase babies in pursuit of participation in the institution of the family.

Mr. GORE. We are running out of time, so I want to ask some other questions and wrap the hearing up.

In the embryo transfer process, Dr. Walters, the embryos are removed from the donor and placed in the uterus of the mother and in some cases more embryos are recovered than can safely be used for fear of creating an unhealthy situation, such as multiple pregnancy.

We had an earlier discussion about the extent to which this is a real problem in the United States, but it certainly is elsewhere. What should be done with the extra embryos created in the process in your view?

Dr. WALTERS. In my view the genetic parents should have the major say in the question of what should be done with the extra embryos. I think that this is an area in which freezing techniques hold out tremendous potential for infertile couples. It will be possible to try to determine what the optimum number of embryos is to transfer during the given ovulatory cycle.

Perhaps it is three or four, but any additional embryos can then be frozen and saved for a subsequent cycle. I think most parents who are desperately trying to have a child should want to go the freezing and preservation route first, rather than adopting any other option.

Mr. GORE. So your preference would be to freeze them and wait until they could be implanted in another mother?

Dr. WALTERS. I guess I am trying to describe what I think most infertile couples will want to do, which is to try to preserve the embryos that are not needed at that particular time for a subsequent implantation into the wife.

Mr. GORE. Would it in your view be an appropriate choice for them to allow the embryos to be used for experimentation or to have them destroyed, assuming that there were research protocols and the objectives of the research were laudable and valuable and so on?

Dr. WALTERS. If the research had been reviewed and approved by the national review committee that I had proposed in my testimony, then I think that the choice by the couple to have the embryos involved in that particular approved research protocol would be ethically acceptable.

Mr. GORE. You stated in your testimony, Professor Gorovitz, that you agreed with that also.

Mr. GOROVITZ. I don't think that is explicit in the testimony. I do agree with that.

Mr. GORE. Dr. McCarthy, you disagree strongly, do you not?

Mr. MCCARTHY. Yes. I made the point in my paper that I would like to look at the freezing process from the point of view of the embryo and ask why do we protect this procedure on what we have all three agreed is a living human being? And I made the analogy to healthy babies. I have friends back at home who had quadruplets, and I can't imagine them freezing two of their babies to have time to nurse the other two, and I make that same analogy to the embryos.

Dr. WALTERS. If I may interject, if the freezing process is improved to the point where most of the embryos come through freezing and thawing safely, then there is no real loss to the embryos by being frozen.

Mr. GORE. Which would be different from freezing a child.

Mr. McCARTHY. I would even say if you could safely freeze the two children out of the four, I don't think you still have what I would call the right to do it, and I would go back to the legal tradition of what we have rights to do to other human beings, if we respect their autonomy. Even if freezing didn't hurt the child or risk it, I would still find the problem with the unconsented projection of that technological procedure on a living human being.

Mr. GORE. We have covered a great deal of territory. There is obviously a great deal more to cover.

Let me recognize the minority counsel.

Mr. LAMINA. Dr. Walters, in your prepared testimony, you noted that only 30.4 percent of all physicians kept permanent records as donors, and you pointed to the need for uniform national standards. Yesterday Professor Kaplan suggested that a national data bank of some kind might be appropriate to fulfill that purpose. If these standards were first set by the Commission as envisioned by Chairman Gore, do you feel that that data bank would best be maintained and operated and perhaps funded more on the State and local level than it would be on some grandiose national data bank?

Dr. WALTERS. Given the mobility of people in our society, it might have to be a national data base. Also, it might include some kind of an upper limit on the number of donations that could be given by any particular semen donor at the present time or any particular egg donor in the future. That certainly is the direction which both Great Britain and France are moving, to try to avoid the problem of an unintended marriage between related people who don't know they are related.

Mr. LAMINA. Professor Gorovitz, you noted in your testimony, to clarify something, if you can, about the HEW Advisory Board. You noted the stark irresponsibility of the administration in that regard. Isn't it true, and clear me up if I am wrong, that the Advisory Board was disbanded in 1979?

Mr. GOROVITZ. I hope that it was clear that I was speaking of all administrations and all Secretaries since then. It is true that the disbanding took place in the previous Presidential administration, and it is also true that the continued refusal to reestablish a board as required by current Department regulations is attributable to the current departmental administration. That claim could have been made at any point since the disbanding.

Mr. GORE. I believe the record shows that Secretary Califano essentially tabled the recommendations and Secretary Harris then disbanded the Board, is that correct?

Mr. GOROVITZ. That is correct.

Dr. WALTERS. There is some evidence that Secretary Califano was moving toward a decision on this matter when he lost his job as Secretary of Health, Education and Welfare.

Mr. GOROVITZ. Which was very shortly after his receipt of the report I believe.

Mr. GORE. And both parties, both administrations, share whatever blame or credit is to be apportioned here, and you would say "blame."

Well, one other question. Dr. Walters, did you make a suggestion in conversations with staff about favoring a guideline wherein true parents are used for these technologies?

Dr. WALTERS. True parents?

Mr. GORE. In other words, stating a preference or a guideline that would mitigate against the involvement of third parties, such as the lavage technique would do?

Dr. WALTERS. I don't recall that statement, but my view is that in cases of necessity, that one member of the couple can't produce viable gametes that then the couple has no recourse if it wants to have a family of its own other than to go outside the family in some way, whether by adopting a child or whether by, so to speak, taking in the gamete from outside the immediate family.

Mr. GOROVITZ. May I address that point as well? I want to endorse that view. I believe that the techniques will be attractive primarily to infertile couples who wish to approximate as closely as they can to the normal situation. For those who are unable to do that, it may be, as Dr. McCarthy has said, that God is the author of life, but we are the copy editors, and I think that we are fully entitled to make the best revisions in the circumstances that we can justify.

Mr. GORE. I know Dr. McCarthy disagrees with that. We will note his disagreement for the record.

Mr. MCCARTHY. Note a frown.

Mr. GORE. Let me thank all three of you for your very helpful testimony and an interesting, informative dialog that we have engaged in.

I want to also thank all of the witnesses who have appeared during both days of these hearings. We are going to continue our inquiry into this issue. We will continue to deliberate on it, and we will have recommendations after close consultation between majority and minority and due process that we follow in this subcommittee.

But I hope that the dialog itself is of some value, and I am very grateful for all who have participated in it.

And, with that, we will stand adjourned.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned subject to the call of the Chair.]

APPENDIX

The Warnock Committee

The Warnock Committee was established in July 1982 with the following terms of reference: "To consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical, and legal implications of these developments; and to make recommendations." It reported on 18 July 1984. Its members were Dame Mary Warnock, Mr Q S Anisuddin, Mr T S G Baker, Dame Josephine Barnes, Mrs M M Carriline, Dr D Davies, Professor A O Dyson, Mrs N L Edwards, Dr W Green-gross, Professor W G Irwin, Professor J Marshall, Professor M C Macnaughton, Dr A McLaren, Mr D J McNeil, Professor K Rawnsley, and Mrs M J Walker. It recommended that:

The licensing body and its functions

- (1) A new statutory licensing authority be established to regulate both research and those infertility services which we have recommended should be subject to control.
- (2) There should be substantial lay representation on the statutory authority to regulate research and infertility services and that the chairman must be a lay person.
- (3) All practitioners offering the services we have recommended should only be provided under licence, and all premises used as part of any such provision, including the provision of fresh semen and banks for the storage of frozen human eggs, semen, and embryos should be licensed by the licensing body.
- (4) Artificial insemination by donor (AID) should be available on a properly organised basis and subject to the licensing arrangements described in chapter thirteen, to those infertile couples for whom it might be appropriate. The provision of AID services without a licence for the purpose should be an offence.
- (5) The service of in vitro fertilisation (IVF) should continue to be available subject to the same type of licensing and inspection as we have recommended with regard to the regulation of AID (see chapter four).
- (6) Egg donation be accepted as a recognised technique in the treatment of infertility subject to the same type of licensing and controls as we have recommended for the regulation of AID and IVF.
- (7) The form of embryo donation involving donated semen and egg which are brought together in vitro be accepted as a treatment for infertility, subject to the same type of licensing and controls as we have recommended with regard to the regulation of AID, IVF, and egg donation.
- (8) The technique of embryo donation by lavage should not be used at the present time.
- (9) The use of frozen eggs in therapeutic procedures should not be undertaken until research has shown that no unacceptable risk is involved. This will be a matter for review by the licensing body.
- (10) The clinical use of frozen embryos may continue to be developed under review by the licensing body.
- (11) Research conducted on human in vitro embryos and the handling of such embryos should be permitted only under licence.
- (12) No live human embryo derived from in vitro fertilisation, whether frozen or unfrozen, may be kept alive, if not transferred to a woman beyond 14 days after fertilisation, nor may it be used as a research subject beyond 14 days after fertilisation. This 14 day period does not include any time during which the embryo may have been frozen.
- (13) Consent be obtained as to the method of use or disposal of spare embryos.
- (14) As a matter of good practice no research should be carried out on a spare embryo without the informed consent of

the couple from whom the embryo was generated, whenever this is possible.

(15) Where trans-species fertilisation is used as part of a recognised programme for alleviating infertility or in the assessment or diagnosis of subfertility it should be subject to licence and that a condition of granting such a licence should be that the development of any resultant hybrid should be terminated at the two cell stage.

(16) The licensing body be asked to consider the need for follow up studies of children born as a result of the new techniques, including consideration of the need for a centrally maintained register of such births.

(17) The sale or purchase of human gametes or embryos should be permitted only under licence from, and subject to, conditions prescribed by the licensing body.

Principles of provision

- (18) As a matter of good practice any third party donating gametes for infertility treatment should be unknown to the couple before, during, and after the treatment, and equally the third party should not know the identity of the couple being helped.
- (19) Counselling should be available to all infertile couples and third parties at any stage of the treatment, both as an integral part of NHS provision and in the private sector.
- (20) In the case of more specialised forms of infertility treatment the consent in writing of both partners should be obtained, wherever possible, before treatment is begun, as a matter of good practice. Any written consent should be obtained on an appropriate consent form.
- (21) The formal consent in writing by both partners should, as a matter of good practice, always be obtained before AID treatment begins. A consent form should be used and thoroughly explained to both partners.
- (22) For the present, there should be a limit of 10 children who can be fathered by one donor.
- (23) In cases where consultants decline to provide treatment they should always give the patient a full explanation of the reasons.
- (24) The NHS numbers of all donors be checked by the clinics where they make their donations against a new centrally maintained list of NHS numbers of existing donors, which is to be held separately from the NHS donor register.
- (25) There should be a gradual move towards a system where semen donors should be given only their expenses.
- (26) In relation to egg donation the principles of good practice we have already considered in relation to other techniques should apply, including the anonymity of the donor, limitation of the number of children born from the eggs of any one donor to 10, openness with the child about his genetic origins, the availability of counselling for all parties, and informed consent.
- (27) It should be accepted practice to offer donated gametes and embryos to those at risk of transmitting hereditary disorders.
- (28) All types of "do it yourself" sex selection kits should be brought within the ambit of control provided by the Medicines Act with the aim of ensuring that such products are safe, efficacious, and of an acceptable standard for use.
- (29) The use of frozen semen in artificial insemination should continue.
- (30) There should be automatic five yearly reviews of semen and egg deposits.
- (31) There should be a maximum of 10 years for the storage of embryos after which time the right to use or disposal should pass to the storage authority.
- (32) When one of a couple dies that right to use or dispose of any embryo stored by that couple should pass to the survivor. If both die that right should pass to the storage authority.

(33) Where there is no agreement between the couple the right to determine the use or disposal of an embryo should pass to the storage authority as though the 10 year period had expired.

Service provision

(34) Funding should be made available for the collection of adequate statistics on infertility and infertility services.

(35) Each health authority should review its facilities for the investigation and treatment of infertility and consider the establishment, separate from routine gynaecology, of a specialist infertility clinic with close working relationships with specialist units, including genetic counselling services, at regional and supraregional level.

(36) Where it is not possible to have a separate clinic, infertility patients should be seen separately from other types of gynaecological patient, wherever possible.

(37) The establishment of a working group at national level made up of central health departments, health authorities, and those working in infertility, to draw up detailed guidance on the organisation of services.

(38) Consideration be given to the inclusion of plans for infertility services as part of the next round of health authority strategic plans.

(39) IVF should continue to be available within the NHS.

(40) One of the first tasks of the working group, whose establishment we recommend in 37, should be to consider how best an IVF service can be organised within the NHS.

Legal limits on research

(41) The embryo of the human species should be afforded some protection in law.

(42) Any unauthorised use of an in vitro embryo would in itself constitute a criminal offence.

(43) Legislation should provide that research may be carried out on any embryo resulting from in vitro fertilisation, whatever its provenance, up to the end of the 14th day after fertilisation, but subject to all other restrictions as may be imposed by the licensing body.

(44) It shall be a criminal offence to handle or to use as a research subject any live human embryo derived from in vitro fertilisation beyond that limit—for example, 14 days after fertilisation.

(45) No embryo which has been used for research should be transferred to a woman.

(46) Any unlicensed use of trans-species fertilisation involving human gametes should be a criminal offence.

(47) The placing of a human embryo in the uterus of another species for gestation should be a criminal offence.

(48) The proposed licensing body promulgates guidance on what types of research, apart from those precluded by law, would be unlikely to be considered ethically acceptable in any circumstances and therefore would not be licensed.

(49) Unauthorised sale or purchase of human gametes or embryos should be made a criminal offence.

Legal changes

(50) The AID child should in law be treated as the legitimate child of its mother and her husband, where they have both consented to the treatment.

(51) A change in the law so that the semen donor will have no parental rights or duties in relation to the child.

(52) Following the English Law Commission, that it should be presumed that the husband has consented to AID, unless the contrary is proved.

(53) The law should be changed so as to permit the husband to be registered as the father.

(54) Legislation should provide that when a child is born to a woman following donation of another's egg the woman giving birth should, for all purposes, be regarded in law as the mother of that child, and that the egg donor should have no rights or obligations in respect of the child.

(55) The legislation proposed should cover children born following embryo donation. (See recommendations 53 and 54).

(56) Legislation should be introduced to render criminal the creation or the operation in the United Kingdom of agencies whose purposes include the recruitment of women for surrogate pregnancy or making arrangements for individuals or couples who wish to utilise the services of a carrying mother; such legislation should be wide enough to include both profit and non-profit making organisations.

(57) Legislation should be wide enough to render criminally liable the actions of professionals and others who knowingly assist in the establishment of a surrogate pregnancy.

(58) It be provided by statute that all surrogacy agreements are illegal contracts and therefore unenforceable in the courts.

(59) Legislation should provide that where a person dies during the storage period or cannot be traced at a review date the right of use or disposal of his or her frozen gametes should pass to the storage authority.

(60) Legislation be introduced to provide that any child born by AIH who was not in utero at the date of the death of its father shall be disregarded for the purposes of succession to and inheritance from the latter.

(61) Legislation be enacted to ensure there is no right of ownership in a human embryo.

(62) For the purposes of establishing primogeniture the date and time of birth and not the date of fertilisation shall be the determining factor.

(63) Legislation be introduced to provide that any child born following IVF, using an embryo that had been frozen and stored, who was not in utero at the date of the death of the father shall be disregarded for the purposes of succession to and inheritance from the latter.

The report contains three expressions of dissent. A leading article appears on p 207.